

# Medical CVI<sup>TM</sup>

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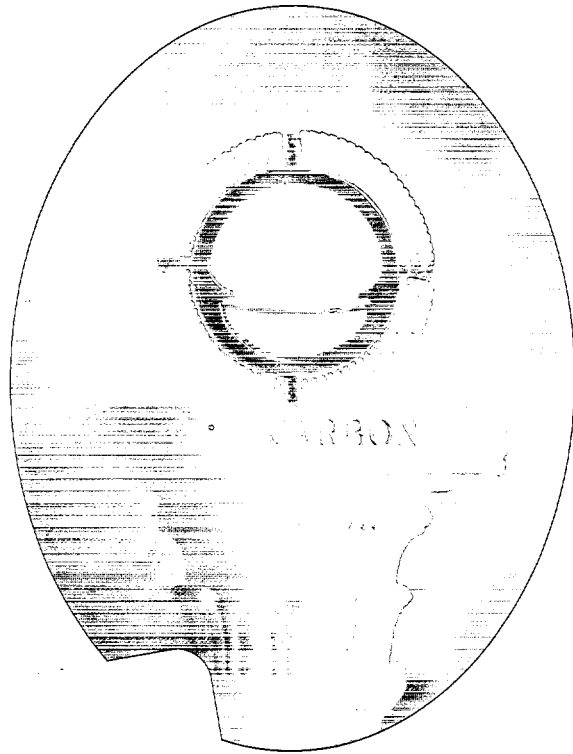
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FINANCIAL

2002 ANNUAL REPORT

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## THE OMNICARBON™ HEART VALVE

Our core product, the Omnicarbon heart valve (pictured on the cover), has been in use outside the United States since 1984. To date, more than 30,000 Omnicarbon valves have been implanted in patients in more than 30 countries. In July 2001, the valve was approved for sale in the United States. Based on more than 18 years of excellent clinical results in Europe, Japan and Canada, the U.S. Food and Drug Administration gave premarket approval for the Omnicarbon 3000 valve for use in the United States — without requiring additional U.S. clinical trials. The Omnicarbon valve results from clinical studies published in peer-reviewed journals, including more than 10,000 patient years of use, have consistently demonstrated significantly fewer design-related complications, such as blood clots and stroke, compared to other mechanical heart valves — providing a significant improvement in a patient's quality of life.

## ABOUT THE COMPANY

Our company is a Minnesota-based heart valve manufacturer that recently launched its Omnicarbon heart valve in the United States. Led by a new management team, we are focused on building a worldwide market in mechanical heart valves and other innovative products for the cardiovascular surgical suite. Our Omnicarbon heart valve has an established market position in a number of key regions of Europe, Asia and the Middle East. Although international markets will continue to play an important role in our results, the recently opened U.S. market for the Omnicarbon valve offers tremendous growth potential. We have a fully integrated manufacturing facility, where we design, test and manufacture all of our products. Our company went public in November 2001 and our units are traded on The Nasdaq SmallCap Market under the symbol "MDCVU."

## FINANCIAL DATA

	Fiscal Year Ended April 30,	
	2002	2001
Net sales	\$ 2,982,198	\$ 2,863,440
Gross profit	872,745	1,059,162
Operating loss	(3,812,556)	(2,934,920)
Net loss	\$ (4,297,665)	\$ (3,238,829)
Diluted loss per share	\$ (0.62)	\$ (0.56)
Diluted shares outstanding	6,980,820	5,787,642
Total shareholders' equity	\$ 4,026,041	\$ 2,429,271

## FORWARD-LOOKING STATEMENTS

This report contains certain forward-looking statements of expected future developments, as defined in the Private Securities Litigation Reform Act of 1995. The forward-looking statements in this report refer to the expectations regarding continuing operating improvement and other matters. These forward-looking statements reflect management's expectations and are based on currently available data; however, actual results are subject to future risks and uncertainties, which could materially affect actual performance. Risks and uncertainties that could affect such performance include, but are not limited to, the following: our ability to fund our significant future capital needs; market acceptance in the U.S. of our Omnicarbon 3000 heart valve; potential reductions in heart valve pricing by our competitors; the costs of licensing and acquiring new products and

technologies; the time and costs involved in obtaining regulatory clearance for our Omnicarbon 4000 heart valve; competing technological and market developments; physician acceptance of our heart valves; dependence upon third party suppliers; and the strength of the mechanical heart valve market. For more detailed information about these risks and uncertainties, please review our Annual Report on Form 10-KSB for the fiscal year ended April 30, 2002.

These events and uncertainties are difficult or impossible to predict accurately and many are beyond our control. We assume no obligation to publicly release the results of any revisions that may be made to any forward-looking statements to reflect events or uncertainties after the date of such statements or to reflect the occurrence of anticipated or unanticipated events.

## DEAR SHAREHOLDERS:

We are pleased to provide you with our first annual report as a public company. Fiscal 2002, which ended April 30, 2002, was a transition year. We made significant progress in positioning our company for long-term growth as a cardiovascular technology leader with a growing, global market presence.

While MedicalCV, Inc. is a new name in the world of health care technology, our company has more than 30 years of experience in designing, developing and manufacturing mechanical heart valves. In fact, we were the pioneer and technology leader in designing the first commercially available heart valve that incorporated pyrolytic carbon technology, which is the gold standard for heart valves today. Our global presence and technology leadership in mechanical heart valves has created a compelling growth opportunity.

## FISCAL 2002 BUSINESS ACHIEVEMENTS

We accomplished several critical goals during fiscal 2002 that will provide the basis for our company's future growth:

- On July 26, 2001, we received premarket approval from the U.S. Food and Drug Administration (FDA) to sell our Omnicarbon™ 3000 heart valve in the United States, enabling us to enter the world's largest geographic market for mechanical heart valves. The Omnicarbon valve has been available internationally for more than 18 years.
- We completed an initial public offering of securities on November 27, 2001, to fund our growth and expansion into the U.S. heart valve market.
- We completed our vertical integration with the installation of new equipment and processes for the production of our next generation Omnicarbon 4000 heart valve, which is currently distributed outside the United States. We are now able to control all aspects of our production, including the manufacture of our own proprietary pyrolytic carbon.
- We also began the FDA approval process for our pyrolytic carbon, which has already been approved in Europe, in order to sell the Omnicarbon 4000 in the U.S. market. We believe that acceptance by the FDA of our pyrolytic carbon process will have a substantial positive effect on our gross margin.

These achievements are part of a long-range strategy to leverage our core heart valve technology in order to create a diversified company offering a broad spectrum of innovative products for the cardiothoracic surgeon.

## GROWTH STRATEGIES

Our management team is focused on growing our company by:

**Enhancing Productivity and Margins.** With the efficiencies we established in our manufacturing process during fiscal 2002, we are poised to achieve significantly improved gross margins in the years ahead. In addition, we now have substantially greater capacity to meet increased global demand for the Omnicarbon valve. Going forward, we believe we are well positioned to be the low-cost producer of pyrolytic carbon valves. As a result, we expect our annual gross margins will approximately double to more than 50 percent during the fiscal year ending April 30, 2003. And we anticipate further improvements in gross margins in fiscal year 2004 and beyond.

**Strengthening Marketing and Sales.** During fiscal 2002, we invested significant resources in building a stronger U.S. presence among cardiothoracic surgeons. Following the U.S. introduction of the Omnicarbon valve, we added several regional managers to ensure execution of our sales and marketing plan. We also reorganized our European distributor network to ensure effective coverage and boost international sales. As gross margins expand, we will allocate further resources to strengthening our worldwide marketing and sales efforts.

These changes began generating sales gains in the 2002 fourth quarter, in which revenue grew 8 percent over the prior-year period. To achieve positive cash flow, we will need to penetrate the U.S. market and increase our share in key market areas of Europe in addition to adding new products.

**Licensing and Acquiring New Products.** We are focused on bringing innovative ideas to the cardiothoracic surgeon that improve on currently accepted surgical procedures. We are actively seeking opportunities to license or acquire complementary technologies.

**Pursuing Clinical Studies on New Anticoagulation Therapies.** Historically, mechanical valve patients have required the continuous use of "blood thinners" to minimize the formation of blood clots. A key long-range goal is to identify effective new regimens of anticoagulation therapy for use with the Omnicarbon valve that have a low risk of complications. We will be investigating different therapeutic options, such as aspirin and other antiplatelet agents.

To this end, we recently reviewed an independent long-term clinical study on the Omnicarbon valve covering a 10-year period with more than 400 patients. The results are encouraging. Patients received a very low rate of anticoagulation therapy in combination with an antiplatelet agent. The postoperative complication rates were extremely low and consistent with historical clinical studies involving Omnicarbon patients who received standard anticoagulation therapy. Due to these favorable results, we are beginning to explore other treatment options.

#### **RETIREMENT OF OUR FOUNDER**

Dr. Adel Mikhail, who founded our company, retired as president and chief executive officer in June 2001. He was instrumental in identifying the strategies that we need to undertake for long-term competitiveness and success.

I wish to thank Dr. Mikhail for his visionary leadership, mentoring and the high level of integrity that he consistently demonstrated during his tenure as our president. I am delighted that he will continue as chairman of the board.

#### **OUTLOOK**

Our goal is to increase revenues and become cash-flow positive by the end of fiscal 2004, maintaining the necessary liquidity to continue to grow. We expect that our operating losses will continue through fiscal 2004 as we expand our manufacturing capabilities, continue increasing our corporate staff to support the U.S. roll-out of our Omnicarbon 3000 heart valve, and add marketing programs domestically and internationally to build awareness of and create demand for our Omnicarbon heart valves. We will require additional financing in fiscal year 2003. We anticipate that we will need to raise between \$3,000,000 and \$4,000,000 of additional equity or debt financing to fund operations and working capital requirements for the next 12 to 18 months. We also will seek to refinance our bank debt before November

2002 to give us additional borrowing capacity and flexibility in funding the growth of our business.

The Omnicarbon valve, its 18 plus years of superior clinical performance and our expanding technology platform will enable us to leverage our position as a provider of leading cardiovascular products, and expand our domestic and international market share.

Our challenge is to build credibility with surgeons regarding the performance of the Omnicarbon valve. Independent clinical studies continue to provide evidence of the Omnicarbon valve's significantly superior performance compared to leading bileaflet valves. This performance is measured by a low rate of the postoperative complications of thromboembolism (e.g., stroke) and bleeding. Based on these clinical studies, patients who receive the Omnicarbon valve have less risk for these serious complications over their lifetimes, reduced by approximately one-half to two-thirds, compared to the other leading mechanical valves. We believe the Omnicarbon valve is a significant clinical improvement in terms of both postoperative complications and improved patient quality of life. After reviewing the Omnicarbon clinical data, the FDA gave premarket approval for sale of the Omnicarbon in the United States without requiring post-approval clinical studies. In addition, the clinical data accepted by the FDA reflects clinical performance consistent with the excellent results published in peer-reviewed journals by many institutions worldwide. We will continue to increase awareness among surgeons and patients regarding the superior clinical benefits of the Omnicarbon valve.

We are grateful to our shareholders, customers and employees for their continuing support and dedication. We look forward to keeping you posted on our progress.

Sincerely,



Blair P. Mowery  
President and Chief Executive Officer  
August 7, 2002

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**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, DC 20549

**FORM 10-KSB**

- ☒ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE FISCAL YEAR ENDED APRIL 30, 2002**
- ☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**Commission File Number 000-33295**

**MedicalCV, Inc.**

(Name of Small Business Issuer in Its Charter)

**Minnesota**

(State or Other Jurisdiction of Incorporation or Organization)

**41-1717208**

(I.R.S. Employer Identification No.)

**9725 South Robert Trail, Inver Grove Heights, Minnesota 55077**

(Address of Principal Executive Offices, including Zip Code)

**(651) 452-3000**

(Issuer's Telephone Number, including Area Code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

**None**

Securities registered pursuant to Section 12(g) of the Exchange Act:

**Units (each consisting of one share of Common Stock, \$0.01 par value, and one redeemable Class A Warrant  
to purchase one share of Common Stock), Common Stock (\$0.01 par value) and  
redeemable Class A Warrants to purchase Common Stock**

(Title of Class)

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. ☐

The issuer's revenues for its most recent fiscal year were \$2,982,198.

The aggregate market value of the common equity held by non-affiliates of the issuer as of July 11, 2002, was approximately \$4,489,419; based upon an average of the bid and asked prices for one unit on such date.

As of July 11, 2002, the issuer had outstanding 7,843,834 shares of common stock. This number includes 1,500,000 units, each consisting of one share of common stock and one redeemable Class A Warrant sold in the issuer's initial public offering.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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*All references in this report to our experience in the development, manufacture and marketing of mechanical heart valves, as well as the number of worldwide implants of heart valves, include the prior operations of Medical Incorporated, incorporated in 1971, and its successor organization, Omnicor, Inc., incorporated in 1989, the assets of which we acquired in 1992.*

*The following discussion contains various forward-looking statements within the meaning of Section 21E of the Exchange Act. Although we believe that, in making any such statement, our expectations are based on reasonable assumptions, any such statement may be influenced by factors that could cause actual outcomes and results to be materially different from those projected. When used in the following discussion, the words "anticipates," "believes," "expects," "intends," "plans," "estimates" and similar expressions, as they relate to us or our management, are intended to identify such forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those anticipated. Factors that could cause actual results to differ materially from those anticipated, certain of which are beyond our control, are set forth under the caption "Management's Discussion and Analysis or Plan of Operation — Cautionary Statement."*

*Our actual results, performance or achievements could differ materially from those expressed in, or implied by, forward-looking statements. Accordingly, we cannot be certain that any of the events anticipated by forward-looking statements will occur or, if any of them do occur, what impact they will have on us. We caution you to keep in mind the cautions and risks described in our Cautionary Statement and to refrain from attributing undue certainty to any forward-looking statements, which speak only as of the date of the document in which they appear.*

## **PART I**

### **ITEM 1 DESCRIPTION OF BUSINESS**

#### **Overview**

We manufacture and market mechanical heart valves known as the Omnicarbon Series 3000 and Series 4000. Omnicarbon heart valves are used to treat heart valve failure caused by heart disease, natural aging, prosthetic heart valve failure and congenital defects. We have been manufacturing and marketing Omnicarbon heart valves since 1984. Approximately 30,000 Omnicarbon heart valves have been implanted worldwide. We manufactured and marketed the Omnicarbon heart valves' predecessor, the Omniscience heart valve, between 1978 and 2000. Approximately 50,000 Omniscience heart valves have been implanted since the late 1970s. Beginning in the early 1970s through 1987, we manufactured and sold the Lillehei-Kaster heart valve, one of the first heart valves sold, which we licensed from the University of Minnesota. There have been approximately 55,000 implantations of the Lillehei-Kaster heart valve worldwide. In total, we have more than 30 years of experience in developing, manufacturing and marketing heart valves, and we have sold more than 135,000 heart valves worldwide.

Other than limited sales of the Omniscience heart valve in the U.S., our sales of heart valves have been primarily to customers in Europe, South Asia, the Middle East and the Far East. In fiscal year 2002, we derived 65.0 percent of our net sales from Europe.

On July 26, 2001, the FDA gave us notice of premarket approval to sell our Omnicarbon 3000 heart valve in the U.S. We are establishing a U.S. sales organization consisting of independent sales representatives who are experienced in marketing products to cardiovascular surgeons, and we have commenced marketing the Omnicarbon 3000 heart valve in the U.S.

Our success will primarily depend on:

- developing and managing our U.S. and global distribution capability;
- developing relationships with cardiovascular surgeons to create awareness of and demand for our products on a worldwide basis;
- capitalizing on the low rate of design-related complications of the Omnicarbon heart valve; and
- capitalizing on our experience of more than 30 years and our quality record, with no design failures or product recalls.

Our company was incorporated in Minnesota on March 30, 1992 under the name CV Dynamics, Inc. In April 1992, we acquired all of the tangible and intangible assets of Omnicor, Inc. Omnicor resulted from the corporate and financial restructuring of a predecessor company called Medical Incorporated. Medical Incorporated was organized in 1971 to develop

and market the Lillehei-Kaster heart valve, which it licensed from the University of Minnesota. Our company changed its name to MedicalCV, Inc. in February 2000.

## **Industry Background**

There are two main types of prosthetic heart valves: mechanical and biological tissue. The main advantage of mechanical heart valves is durability because such devices are made from low-wear metal and carbon materials. They generally outlast the patient's lifetime. However, in order to prevent the formation of blood clots, mechanical heart valves require the continuous use of blood thinners. Biological tissue heart valves are valves made from animal or cadaver tissue or, in some cases, the patient's own tissue. Tissue heart valves generally have lower durability but also a lower risk of blood clotting compared to mechanical heart valves. If a tissue heart valve fails due to deterioration or calcification, for example, a new heart valve must be implanted, requiring additional open heart surgery. Tissue heart valves are generally prescribed for patients who are less tolerant to blood thinners, such as patients with gastrointestinal ulcers or liver dysfunction, elderly patients, women in child-bearing years and very active people.

Cardiovascular surgeons generally choose a particular type of mechanical heart valve based upon a number of factors. A principal factor is the potential formation of blood clots resulting from the poor flow of blood on certain areas of the heart valve. A clot forming on the heart valve, known as valve thrombosis, can impair the performance of the heart valve. If a clot detaches itself and moves through the bloodstream, it can result in arterial blockage, known as thromboembolism, or stroke. To minimize thromboembolism, a mechanical heart valve implant patient is given doses of blood thinners, which may increase the risk of bleeding and other complications. In addition, mechanical heart valves may cause varying degrees of red blood cell destruction, known as hemolysis, which is tolerable by a majority of patients. Another factor is the performance and efficiency of the heart valve in terms of loss of cardiac energy or "cardiac work" required to move blood through the heart valve orifice. Lower complication rates translate into better quality of life for the patient and reduced medical treatment costs.

Hospitals and clinic administrators have been increasingly influential in medical device purchasing decisions due to the increasing emphasis on medical cost containment. The price of a mechanical heart valve and the costs resulting from the treatment of complications affect cost effectiveness.

Our Omnicarbon heart valves are designed to replace heart valves that have been made defective by disease or congenital origin. Cardiovascular disease is one of the most prevalent diseases in the world and is a leading cause of death in humans. The aging population in most developed countries will fuel the market for cardiovascular implants. Developing countries and eastern European countries are expected to increase spending on health care and may increase their consumption of mechanical heart valves due to the prevalence of rheumatic fever and other diseases. These global markets for cardiovascular devices are characterized by large multinational manufacturers and industry consolidation. Among the major product segments are pace makers, heart valves, angioplasty products and coronary stents. A number of the major manufacturers, such as Medtronic and St. Jude, have medical device lines which include all or most of these products.

The bileaflet mechanical heart valve, a valve with two moving leaflets which allow the blood to flow in one direction, is the world's most frequently implanted prosthetic heart valve and accounts for most heart valve sales in the U.S. heart valve replacement market. The bileaflet mechanical heart valve manufactured by St. Jude has been implanted in over one million patients to date, according to the manufacturer. Despite a clear market preference for bileaflet mechanical heart valves, we believe that we will be able to increase our market position with our Omnicarbon heart valves. Omnicarbon heart valves are the only all-carbon monoleaflet mechanical heart valves. A monoleaflet valve has one moving leaflet which allows the blood to flow in one direction. In clinical studies conducted in Europe, Canada and Japan, the Omnicarbon design has consistently demonstrated lower rates of thromboembolism, valve thrombosis, blood thinner-related bleeding and hemolysis than the two market leaders.

Potential complications or side effects with all mechanical heart valve implants include, but are not limited to:

- thromboembolism and valve thrombosis, resulting in minor stroke;
- hemorrhage;
- deterioration of suture attachments of heart valve to surrounding tissue;
- tissue interference with heart valve function; and



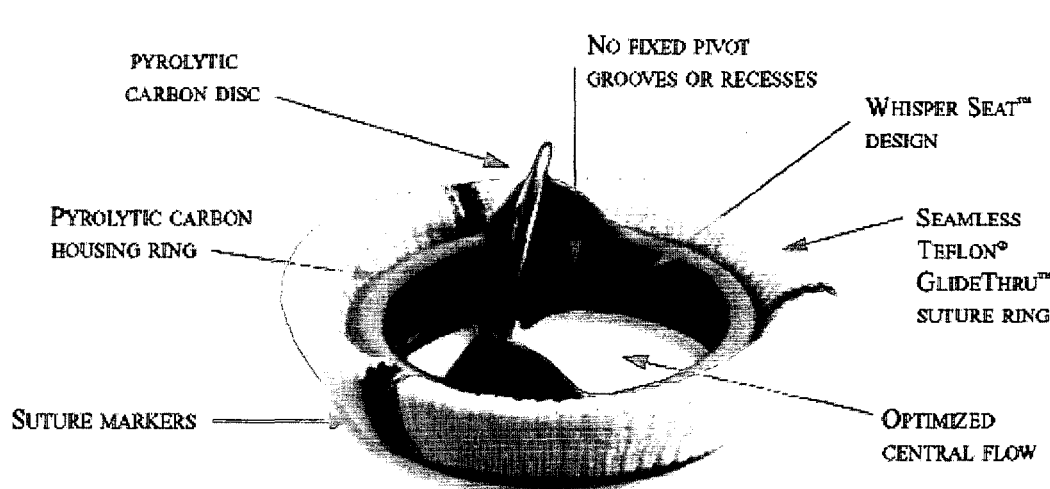
- mechanical failure of the heart valve.

## Our Market Opportunity

We believe that the low complication rates of our Omnicarbon heart valves and our experience in the heart valve field will enable us to build market share in the U.S. and Canada and to increase market share internationally. Our strategy is to create awareness of our products and their advantages among cardiovascular surgeons, organizations which make purchasing decisions for medical devices and third party payers who pay for such treatment. To communicate with these groups, we are using our own corporate marketing personnel, sales managers, independent sales representatives and clinical advisory board members. In addition, we intend to support clinical studies, create state-of-the-art marketing material, exhibit our products and clinical results at all major cardiovascular meetings, strategically advertise in the major cardiovascular journals, develop a dual physician and patient enhanced website and invite interested surgeons to visit our facility and attend in-house presentations.

## Product Description

Our Omnicarbon all-carbon monoleaflet mechanical heart valves consist of a rotatable housing ring within a compliant suture ring, which adapts to the native annulus or natural valve rim, and a curved, freely rotating disc, which is retained by two shields extending from the ring. The disc pivot axis forms two orifices, one larger than the other, with a maximum opening angle of 80 degrees. The example shown below is larger than actual size.



## Omnicarbon Series Heart Valve

The housing and disc of the Omnicarbon 3000 and 4000 heart valves are made of pyrolytic carbon, which offers blood compatibility and durability. Pyrolytic carbon components represent the largest portion of our production costs. In 1999, we began manufacturing Omnicarbon heart valves utilizing our own proprietary pyrolytic carbon coating process. These heart valves, known as Omnicarbon 4000 heart valves, represent the heart valves we currently sell in markets other than the U.S. and Japan.

At this time, we do not have clearance from the FDA to manufacture Omnicarbon 4000 heart valves for sale in the U.S. Therefore, we use pyrolytic carbon components purchased from Sulzer Carbomedics in the heart valves we sell in the U.S. These heart valves, known as Omnicarbon 3000 heart valves, represent the heart valves we have now begun to sell in the U.S. and Japan.

We intend to apply for FDA clearance of our pyrolytic carbon process in order to manufacture carbon components for the sale of Omnicarbon 4000 heart valves in the U.S. We believe that we can obtain premarket approval from the FDA for our pyrolytic carbon process by late 2004. We further believe that approval of our pyrolytic carbon coating process will be important to our future success because it will enable us to substantially decrease the manufacturing cost of Omnicarbon heart valves sold in the U.S. If we receive such clearance, we plan to discontinue selling Omnicarbon 3000 heart valves and begin selling Omnicarbon 4000 heart valves in the U.S. We cannot assure you, however, as to when or whether we will receive FDA clearance.

## Marketing and Sales

Our sales and marketing plan focuses on:

- creating widespread awareness of and demand for our Omnicarbon heart valves among cardiovascular surgeons, cardiologists and medical treatment organizations which make medical device purchasing decisions;
- capitalizing on our quality record, with over 135,000 heart valves having been implanted over the last 30 years without design failure or product recall;
- creating awareness of the superior clinical performance of our Omnicarbon heart valves, including lower complication rates of thromboembolism, bleeding and hemolysis compared to other mechanical heart valves, including those of the two market leaders;
- offering quality service, rapid product delivery and competitive pricing; and
- capitalizing on trends which influence the worldwide cardiovascular market, such as the increased number of cardiovascular surgical procedures due to the aging population and increases in health care spending in developing countries and eastern Europe.

Our goal is to reach cardiovascular surgeons, organizations that make purchasing decisions with regard to medical devices and third party payers who pay for such treatment to make them aware of the advantages of our product. To reach these groups, we are using our corporate marketing and technical personnel, sales managers, sales representatives and clinical advisory board members. In addition, we will:

- support various clinical studies;
- furnish state-of-the-art marketing materials;
- exhibit our products at all major cardiovascular meetings;
- strategically advertise in the major cardiovascular journals;
- provide a website targeting both physicians and patients; and
- emphasize facility visits by surgeons using or interested in our products.

*United States.* As of April 30, 2002, our U.S. sales team consisted of our senior vice president — sales and marketing, a director of sales, a field sales manager, and independent sales representatives located throughout the U.S., who are experienced in marketing medical devices to cardiothoracic surgeons. We provide to our sales representatives training programs, marketing aides, educational materials for the medical community and sales literature. We are committing substantial resources to train, support and motivate our U.S. sales team to introduce the Omnicarbon heart valve and advance sales of Omnicarbon 3000 heart valves in the U.S.

*International.* We market and sell our products primarily in Europe, South Asia, the Middle East and the Far East. As of April 30, 2002, we had a network of over 35 independent distributors selling Omnicarbon Series 3000 and Series 4000 heart valves in these geographic areas.

Our customary business practice is to enter into three-year exclusive distributor contracts with new distributors, which are linked to annual minimum sales goals. In addition, our distributors are required to attend annual training meetings to ensure competency in heart valve surgery, to promote the Omnicarbon heart valve at local medical meetings and to call on prospective customers on a regular basis.

## **Manufacturing and Supply**

We manufacture and assemble Omnicarbon heart valves and other products at our facility in Inver Grove Heights, Minnesota. We manufacture our Omnicarbon 4000 heart valve in its entirety, utilizing our proprietary pyrolytic carbon process. We assemble our Omnicarbon 3000 heart valve using our own proprietary suture ring and pyrolytic carbon components purchased from Sulzer Carbomedics.

Pyrolytic carbon has been used in mechanical heart valves for approximately 30 years. Pyrolytic carbon coating on such components as heart valve housings and heart valve leaflets is formed by the pyrolysis of carbon. We began to develop our own pyrolytic carbon coating process in 1995. Our process involves heating propane to a high temperature, which breaks it down into hydrogen and carbon. The hydrogen is then vented and the carbon atoms are deposited on the surface of graphite substrate shaped as a disc or housing ring. Pyrolytic carbon coating has greater blood compatibility compared to other materials historically used in heart valves, resulting in a lower incidence of thromboembolism and other potential complications. Pyrolytic carbon components have been tested to last longer than any patient's lifetime. We also manufacture knitted, seamless Teflon tubings which are used in constructing suture rings to correspond with various heart valve sizes. We have developed and instituted a complete, vertically integrated manufacturing and quality control system for our Omnicarbon 4000 heart valves. The pyrolytic carbon components we purchase from Sulzer Carbomedics for our Omnicarbon 3000 heart valves are tested under the same rigorous requirements as our Omnicarbon 4000 heart valves.

We ship all of our products from our facility in Inver Grove Heights, Minnesota, either to distributors or directly to hospitals. We generally do not have a significant backlog of orders and maintain a sufficient inventory of products which enables us to ship within 24 to 48 hours of receipt of orders.

We assemble our Omnicarbon 3000 and 4000 heart valves in a controlled clean room environment in our facility, where we fabricate the sewing cuff, conduct final cleaning and inspection and package the finished heart valves. The packaged heart valves are then sterilized and quarantined. They must pass sterility tests before being released for shipping. We believe that our manufacturing facilities meet applicable standards for "good manufacturing practices" established by the FDA and other applicable government standards. In the normal course, our facility is frequently subject to inspections by the FDA and foreign regulatory agencies in connection with their reviews of our products.

We believe that the raw materials and components used in manufacturing our Omnicarbon 4000 heart valves are readily available. However, we purchase the pyrolytic carbon parts for our Omnicarbon 3000 heart valves only from Sulzer Carbomedics, a supplier whose materials and manufacturing meet FDA regulations for inclusion in our medical devices. We purchase these components under an original equipment manufacturing supply contract which expires in December 2003. Under this contract, we are obligated to purchase minimum quantities of our carbon-coated components exclusively from Sulzer Carbomedics during the term of the agreement. These components are manufactured pursuant to our specifications. Sulzer Carbomedics has agreed to supply our requirements and, to date, we have not experienced shortages or significant delays in their supply of components. Sulzer Carbomedics may terminate this contract if we fail to make any payment promptly when due, or if we infringe any patent of Sulzer Carbomedics by making or having made any product or using any method covered by such patent in or in preparation for commercial sale of cardiac valve prostheses, or if we are in default of any of our material obligations under this contract. We currently depend upon Sulzer Carbomedics for these critical components and have no other supplier of pyrolytic carbon parts for our Omnicarbon 3000 heart valves.

## **Product Development and Research**

There is a clear market preference for bileaflet designs. Although we believe, and the scientific literature supports, that this preference is not scientifically justified, we have undertaken certain product development efforts towards developing a bileaflet heart valve. We are also planning to expand our line of cardiac surgery products by developing and acquiring new products that can be marketed to cardiovascular surgeons.

*Novadyne bileaflet heart valve development project.* To strengthen our heart valve portfolio, we have initiated the Novadyne bileaflet heart valve development project. Successful completion of the Novadyne project would enable us to offer monoleaflet and bileaflet heart valves manufactured with our proprietary pyrolytic carbon process. Our Novadyne design incorporates features learned from more than 30 years of experience with the Lillehei-Kaster, Omniscience and Omnicarbon monoleaflet heart valves and from analyzing existing bileaflet design successes and failures of competitive products. The Novadyne project involves an all-carbon bileaflet heart valve design with unique open-channel dynamic pivots that are self-washing. This design is intended to eliminate deep pivot recesses and associated poor flow characteristics which are regarded as the cause of thromboembolic complications in bileaflet designs. These new design features induce pivot washing, which is intended to reduce thromboembolism. We have been issued three U.S. patents for bileaflet heart valves.

*Blood filters.* We have the technology base and manufacturing capability to produce a broad line of transfusion and extra-corporeal blood filters. We currently market our existing blood filter only in Japan, and sales of this product are immaterial. We have received FDA clearance to market our blood filter in the U.S., but have determined that we have only a limited market for such product in the U.S. We are exploring the development of additional filters, including a heparin filter and a complement mediator filter, in order to develop a broader line of products for cardiothoracic surgeons. These devices are used in cardiopulmonary bypass procedures, the number of which is now estimated to be 800,000 per year on a worldwide basis.

Our research and development expenses principally consist of engineering costs. Our research and development expenses were \$496,685 in fiscal year 2002, compared to \$800,625 in fiscal year 2001. Research and development costs relate primarily to product and process development initiatives. We anticipate that research and development and clinical and regulatory expenses will continue to rise in future periods.

### **Patents and Proprietary Rights**

We believe strongly in protecting our intellectual property and will seek patent protection for new products and processes under development whenever we believe it is advisable. As of April 30, 2002, we had three U.S. patents, all relating to our bileaflet heart valve under development. We also have two pending foreign patent applications. We have filed U.S. and foreign patent applications for the process and processing equipment used in our pyrolytic carbon coating process and are awaiting further patent prosecution in relation to these applications. Our current patents will begin to expire in 2015. We cannot assure you that any patents held by us will be valid, enforceable or otherwise of value to us in relation to our competitors or the market in general, or that any patent for which we have applied or may apply will be granted.

We have no patents covering the design of our Omnicarbon heart valves and we do not intend to seek such patents. Because heart valves of this design have been sold in the marketplace for many years, the product is no longer patentable. We do not believe that protecting the design of a heart valve is critical for the success of a heart valve manufacturer. We believe that the key to success lies in a vertically integrated infrastructure, the soundness of design, clinical safety and efficacy of performance of the heart valve and the manufacturer's ability to successfully build product awareness.

We also rely upon trade secrets and proprietary know-how. We require our technical employees and consultants to agree in writing to keep our proprietary information confidential and, with certain limitations, to assign all inventions relating to our business to us.

We have used, and therefore claim common law rights in, the following trademarks: *MedicalCV*, *Omnicarbon*, *Omniscience*, *Interface*, *Whisper Seat*, *GlideThru*, *UltraPure*, *UPP Carbon* and *Medical Incorporated*. We also have a federal registration for the mark: *Omniscience*.

### **Government Regulation**

The medical devices we manufacture and market are subject to regulation by the FDA and, in most instances, by state and foreign authorities or their designated representatives. Under the U.S. Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, as a manufacturer of medical devices, we must comply with policies and procedures that regulate the manufacturing, composition, labeling, testing, packaging and distribution of medical devices. In addition, medical devices are subject to different levels of government approval requirements, the most comprehensive of which requires the completion of an FDA approved clinical evaluation program and submission, and approval of a premarket approval application before a device may be commercially marketed. The FDA also conducts inspections before approving a premarket approval application to determine compliance with the quality system regulations which cover manufacturing and design. Our heart valves are subject to this level of approval. On July 26, 2001, we received notice of premarket approval from the FDA with respect to our Omnicarbon 3000 heart valve.

After premarket approval is received, the FDA may require testing and surveillance programs to monitor the effectiveness of approved products which have been commercialized. It has the power to prevent or limit further marketing of a product based on the results of such post-marketing programs. In addition, the FDA may, at any time after the approval of a premarket approval application, conduct periodic inspections to determine compliance with good manufacturing practice regulations and current medical device reporting regulations. If the FDA concludes that we are not in compliance with applicable laws or regulations, it can institute proceedings to:

- seize our product;
- issue a product recall;
- impose operating restrictions; and/or
- assess civil penalties or recommend criminal prosecution.

The FDA also regulates recordkeeping for medical devices and reviews hospital and manufacturers' required reports of adverse experiences to identify potential problems with FDA-authorized devices.

Some of the products that we intend to develop and market can be cleared under Section 510(k) of the Federal Food, Drug and Cosmetic Act. The process of obtaining Section 510(k) clearance typically requires less time and expense than the premarket approval process. Section 510(k) clearance normally takes from six months to one year, but can take years, and generally requires the submission of supporting data, which in some cases can be extensive. In addition, the FDA may require review by an advisory panel as a condition for Section 510(k) clearance. We intend to continue to rely on the Section 510(k) process with regard to certain products, such as any additional blood filters we may develop. However, we may develop and produce enhancements to our existing blood filter and heart valves that will require clearance under the FDA's more lengthy and expensive premarket approval process, which can take a number of years and can require extensive supporting documentation. If we encounter difficulties in the premarket approval process, the commercial marketing of any future heart valves could be substantially delayed or prevented.

International sales of our products are also subject to extensive regulation. Foreign regulatory bodies have established varying regulations governing product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. Generally, the extent and complexity of the regulation of medical devices is increasing worldwide, with regulations in some countries already nearly as extensive as those in the U.S. This trend may continue, and the cost and time required to obtain marketing approval in any given country thus may increase. We cannot assure you that any foreign approvals will be allowed on a timely basis, or at all.

To market our products in countries of the European Union, we are required to obtain CE mark certification. CE mark certification is the international symbol of adherence to certain quality assurance standards and compliance with European medical device directives. In June 1995, we received ISO 9001 and EN 46001 qualification of our quality system for our manufacturing processes in our facility in Inver Grove Heights, Minnesota. We obtained the CE mark for our Omnicarbon 3000 heart valve on June 27, 1995, for our Omniscience heart valve on July 15, 1998 and for our Omnicarbon 4000 heart valve on April 8, 1999.

We derive substantially all of our revenues from sales of Omnicarbon heart valves outside the U.S. Our inability, or the failure of our foreign distributors, to comply with varying foreign regulations or the imposition of new regulations could restrict the sale of our products internationally and thereby materially adversely affect our business, financial condition, operating results and cash flows.

## **Competition**

The mechanical heart valve market is highly competitive, with St. Jude supplying the majority of mechanical heart valves sold worldwide. Other competitors in the mechanical heart valve field include Sulzer Carbomedics, Edwards Life Sciences, Medtronic, Sorin Biomedica spa in Italy, ATS Medical, Inc. and MCRI, Inc. Many of these competitors have:

- greater name and product recognition;
- greater financial, manufacturing and marketing resources;
- greater regulatory compliance capabilities;
- stronger physician relationships; and
- broader and more established product lines than we have.

Most of these competitors market bileaflet heart valves, for which there is currently a dominant market preference. Some of these competitors also market tissue heart valves and are currently pursuing new mechanical heart valve designs, biocompatible coatings for mechanical heart valves, longer lasting tissue heart valves and surgical alternatives to implanting prosthetic heart valves. It is possible that developments by our competitors could render our current or proposed heart valves obsolete. We cannot assure you that we will be able to compete against such competitors.

### **Product Liability and Insurance**

The development and sale of medical devices entails significant risk of product liability claims and, sometimes, product failure claims. Although over 30,000 of our Omnicarbon heart valves have been implanted with no design failures, and although there is significant clinical data to reasonably convince us that these products are safe and effective, we face an inherent business risk of financial exposure to product liability claims if the use of our products results in personal injury or death. We also face the possibility that defects in the design or the manufacturing of our products could necessitate a product recall. We have not, to date, experienced significant product liability claims, and we have never had a product recall. We cannot assure you, however, that we will not experience losses in the future due to product liability claims or recalls.

We currently maintain product liability insurance with coverage limits of \$5,000,000 in the aggregate annually. We cannot assure you that such coverage limits will be adequate. In addition, trends regarding claims and damages in the medical device industry could increase the cost of insurance, which is already expensive, and may make insurance coverage difficult for us to obtain in the future on acceptable terms, or at all. Any claims against us, regardless of their merit or eventual outcome, could involve a significant financial outlay in connection with the investigation of claims or payment of deductible amounts to insurance companies. A significant claim could involve payment of an amount which could have a material adverse effect upon our business, financial condition, operating results and cash flows. In addition, adverse publicity resulting from product liability litigation may materially and adversely affect us, regardless of whether the claims are valid or whether we are liable.

### **Employees**

As of April 30, 2002, we had 44 full-time employees, including 25 who were in manufacturing and research and development, and the remainder of whom were in administration and sales and marketing. We are not a party to any collective bargaining agreement and believe that our relations with employees are good.

## **ITEM 2 DESCRIPTION OF PROPERTY**

We own a 55,000 square foot production and administrative facility located on 19 acres of land in Inver Grove Heights, a suburb of Saint Paul, Minnesota. Our facility has approximately 8,000 square feet of general office space and over 32,000 square feet of manufacturing space. Our facility also includes over 9,500 square feet of controlled environment rooms and necessary support areas for producing and assembling our products. Our facility is subject to inspection by the FDA and foreign regulatory agencies as part of their product marketing clearance and surveillance programs. This facility, in conjunction with other company assets, secures our indebtedness to Associated Bank Minnesota. As of April 30, 2002, we owed Associated Bank Minnesota a principal amount of \$2,500,000 under the terms of our line of credit.

## **ITEM 3 LEGAL PROCEEDINGS**

As of April 30, 2002, we were not a party to any material litigation.

## **ITEM 4 SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

Not applicable.

### **Executive Officers of the Registrant**

The following table provides information with respect to our executive officers as of April 30, 2002. Each executive officer has been appointed to serve until his successor is duly appointed by the board or his earlier removal or resignation from office.

<u>Name</u>	<u>Age</u>	<u>Position with MedicalCV</u>
Blair P. Mowery	56	President, Chief Executive Officer and Director
Jules L. Fisher	48	Chief Financial Officer
Allan R. Seck	56	Senior Vice President - Sales and Marketing

*Blair P. Mowery* became our President and Chief Executive Officer in June 2001 and was appointed to our board of directors in July 2001. After serving our company as an independent advisor through his wholly-owned company, Bioscrene Ltd., from February 1996 to August 1996, he joined us in August 1996 as Vice President - Business Development and was promoted to Chief Operating Officer in 1999. From April 1991 through December 1993, Mr. Mowery was President and Chief Operating Officer of GalaGen, Inc., a biopharmaceutical company. From March 1987 to March 1991, he was President of Procor Technologies, a joint venture with Abbott Ross Laboratories and the predecessor company to GalaGen.

*Jules L. Fisher* became our Chief Financial Officer in January 2002. From October 1996 to December 2001, Mr. Fisher served as Vice President and Chief Financial Officer of Minntech Corporation, a manufacturer of medical supplies and devices, sterilants, and filtration and separation products primarily for kidney dialysis, open-heart surgery and endoscopy. From August 1991 to October 1996, he held the position of Director, Operations Accounting for U.S. Surgical Corp. Mr. Fisher also served as Director, Financial Reporting and Analysis in the Pharmaceutical Group of Bristol-Myers Squibb Company from May 1987 to February 1991.

*Allan R. Seck* joined our company in May 1999 as Vice President - Sales and Marketing. In March 2001, he was promoted to Senior Vice President - Sales and Marketing. From May 1996 until May 1999, Mr. Seck served as Vice President - Sales and Marketing for AVECOR Cardiovascular, Inc., where he was responsible for sales, marketing, customer service, technical support, customer education and shipping. He has also held senior management positions with Biomedicus, Inc., the cardiopulmonary division of Medtronic, and Johnson & Johnson Cardiovascular.

## PART II

### ITEM 5 MARKET FOR COMMON EQUITY AND RELATED SHAREHOLDER MATTERS

Our units have been listed on The Nasdaq SmallCap Market under the symbol "MDCVU" since the completion of our initial public offering in November 2001. The following table sets forth the approximate high and low closing prices for our units for the periods indicated as reported by The Nasdaq SmallCap Market. Such quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

Period	High	Low
Fiscal Year 2002		
Third Quarter (commencing November 21, 2001).....	\$ 4.50	\$ 3.00
Fourth Quarter .....	\$ 3.70	\$ 2.35

As of April 30, 2002, we had 92 shareholders of record and approximately 453 beneficial owners.

We have never declared or paid cash dividends. We currently intend to retain future earnings, if any, to operate and expand our business, and we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends in the future will be at the discretion of our board of directors and will depend upon our results of operations, earnings, capital requirements, contractual restrictions and other factors deemed relevant by our board.

#### Sales of Unregistered Securities during the Fourth Quarter of Fiscal Year 2002

Not applicable.

#### Use of Proceeds from Registered Securities

Our Registration Statement on Form SB-2 (File No. 333-68884) was declared effective by the SEC on November 20, 2001.

Through April 30, 2002, we had incurred total expenses of \$1,353,515 in connection with our initial public offering. Such expenses represent: (1) \$675,000 in underwriting discounts and commissions paid to our underwriter, (2) \$202,500 in expenses paid to our underwriter, (3) \$206,201 in fees and expenses paid to our attorneys, (4) \$131,910 in fees and expenses paid to our accountants, (5) \$68,547 paid to our financial printer, (6) \$7,167 in NASDAQ listing fees, (7) \$53,846 in blue sky legal and filing fees, (8) \$4,744 in SEC registration fees, and (9) \$3,600 in transfer agent fees. None of the foregoing expenditures represent direct or indirect payments to our directors, officers or their associates, to persons owning 10 percent or more of any class of our equity securities, or to our affiliates.

After deducting the total expenses of our initial public offering, our net proceeds were approximately \$5,396,485. We estimate that we used \$2,909,000 of the initial public offering net proceeds through April 30, 2002. Such uses of proceeds represent: (1) \$2,180,000 to fund sales and marketing initiatives, including general and administrative expenses to support infrastructure and engineering and regulatory expenses to support operations, (2) \$50,000 to fund working capital requirements, (3) \$139,000 to purchase capital equipment, (4) \$500,000 to repay bridge notes, and (5) \$40,000 in advances to UROPACE.

### ITEM 6 MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

*The following discussion contains various forward-looking statements within the meaning of Section 21E of the Exchange Act. Although we believe that, in making any such statement, our expectations are based on reasonable assumptions, any such statement may be influenced by factors that could cause actual outcomes and results to be materially different from those projected. When used in the following discussion, the words "anticipates," "believes," "expects," "intends," "plans," "estimates" and similar expressions, as they relate to us or our management, are intended to identify such forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those anticipated. Factors that could cause actual results to differ materially from those anticipated, certain of which are beyond our control, include those discussed in our Cautionary Statement as well as those discussed elsewhere in this Form 10-KSB.*

*Our actual results, performance or achievements could differ materially from those expressed in, or implied by, forward-looking statements. Accordingly, we cannot be certain that any of the events anticipated by forward-looking*



*statements will occur or, if any of them do occur, what impact they will have on us. We caution you to keep in mind the cautions and risks described our Cautionary Statement as well as those discussed elsewhere in this Form 10-KSB and to refrain from attributing undue certainty to any forward-looking statements, which speak only as of the date of the document in which they appear.*

## **Overview**

We manufacture and market mechanical heart valves known as the Omnicarbon Series 3000 and Series 4000. Our heart valves are used to treat heart valve failure caused by the aging process, heart diseases, prosthetic heart valve failure and congenital defects. To date, we have distributed the Omnicarbon 3000 and 4000 heart valves primarily in Europe, South Asia, the Middle East and the Far East. In fiscal year 2002, we derived 65.0 percent of our net sales from Europe. As an innovator of heart valve technology, we have more than 30 years of experience in developing, manufacturing and marketing five generations of heart valves, and we have sold more than 135,000 heart valves worldwide.

On July 26, 2001, the FDA gave us notice of premarket approval to sell our Omnicarbon 3000 heart valve in the U.S., the largest geographic market for mechanical heart valves. In anticipation of FDA premarket approval, we invested in our sales and marketing infrastructure, including adding sales management to our staff in fiscal year 2001 and recruiting field sales representatives to call on domestic surgery centers in the U.S. Based upon our Omnicarbon heart valve's 17 years of implants in patients in Europe, we believe that we can establish a competitive position in the mechanical heart valve industry in the U.S. and leverage this position into other critical areas of cardiothoracic surgery. We also expect that our ability to market the Omnicarbon 3000 heart valve in the U.S. will favorably affect our international sales, as many cardiovascular surgeons and others who make purchasing decisions are aware of the FDA's rigorous premarket approval process and consider it to be a validation of the safety and efficacy of medical devices. Our company had its first implant of the Omnicarbon 3000 heart valve in the U. S. in December 2001.

The worldwide heart valve market is dynamic and highly competitive. In addition, technology and competitive offerings, such as new tissue heart valves, place increased pressure on us as we seek to increase our market share and revenue. For more information regarding these risks, you should review our Cautionary Statement.

## **Critical Accounting Policies**

*The preparation of our financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. We believe our estimates and assumptions are reasonable; however, actual results and the timing of the recognition of such amounts could differ from those estimates. We have identified the following critical accounting policies and estimates utilized by management in the preparation of our financial statements: revenue recognition, deferred income tax assets, the accounts receivable allowance for doubtful accounts, and inventory obsolescence. Actual amounts could differ significantly from management's estimates.*

**Revenue Recognition.** We recognize revenue using guidance from SEC Staff Accounting Bulletin No. 101 "Revenue Recognition in Financial Statements." Revenue from the sale of our mechanical heart valves is recognized provided that we have received a purchase order, the price is fixed, title has transferred, collection of the resulting receivable is probable and there are no remaining obligations. Transfer of title occurs for substantially all sales upon shipment. Our products are not subject to any customer acceptance process. There are no rights of return unless the product does not perform according to specifications.

**Deferred Income Tax Assets.** In assessing the realizability of our deferred tax assets, management considers whether it is more likely than not that our deferred income tax assets will be realized. The ultimate realization of deferred income tax assets is dependent on the generation of future taxable income, which must occur prior to the expiration of our net operating loss and credit carryforwards, which comprise the majority of the deferred tax assets. As of April 30, 2002, we have established a valuation allowance of \$5,027,700 to fully offset our deferred tax assets due to the inherent uncertainty of predicting the sufficiency of future taxable income necessary to realize these deferred tax assets, particularly in light of our recent history of significant operating losses. In addition, future utilization of available net operating loss carryforwards may be limited under Internal Revenue Code 382 as a result of future changes in ownership.

**Account Receivable Allowance.** In determining the adequacy of our allowance for doubtful accounts, management considers a number of factors, including the aging of our receivable portfolio, customer payment trends, the financial condition of our customer and economic conditions in our customers' countries. Our analysis in determining the allowance for doubtful

accounts is performed by management on a customer-by-customer basis. Although our recorded allowance includes our best estimates, we cannot predict the resolution of these matters with certainty.

**Inventory Obsolescence.** In determining the appropriate carrying value of our inventories, management considers a number of factors, including the aging of our inventory, recent sales trends, industry market conditions and economic conditions. Our analysis requires us to estimate revenues by type of mechanical heart valve. For example, we have expected a decline in Omniscience heart valves, which has been a consideration in the valuation of these items in our inventory. Although adjustments to the carrying value of our inventories reflect our best estimates, the estimates require a large degree of judgment.

## Selected Financial Data

	Years ended April 30,	
	2002	2001
<b>Statement of Operations Data:</b>		
Net sales.....	\$ 2,982,198	\$ 2,863,440
Cost of goods sold.....	2,109,453	1,804,278
Gross profit.....	872,745	1,059,162
Total operating expenses.....	4,685,301	3,994,082
Net loss.....	(3,812,556)	(2,934,920)
Basic and diluted net loss per share.....	(.62)	(.56)
Weighted average number of shares outstanding.....	6,980,820	5,787,642
<b>Balance Sheet Data:</b>		
Total current assets.....	\$ 6,441,819	\$ 3,536,926
Total current liabilities.....	3,689,594	929,876
Working capital.....	2,752,225	2,607,050
Total assets.....	8,091,226	5,218,638
Long-term debt and capital lease obligations, including current portion.....	2,977,906	1,963,503
Total shareholders' equity.....	4,026,040	2,429,271
<b>Statement of Cash Flows Data:</b>		
Net cash used in operating activities.....	\$ (3,186,805)	\$ (2,510,698)
Cash and cash equivalents at end of year.....	2,781,675	111,977
<b>General Data and Ratio:</b>		
Current ratio.....	1.7	3.8
Gross profit margin on net sales.....	29.3%	37.0%

## Results of Operations for the Fiscal Years Ended April 30, 2002 and 2001

**Net Sales.** Net sales in the year ended April 30, 2002 increased 4.1 percent to \$2,982,198 from \$2,863,440 in the prior year. The increase was primarily attributable to higher Omnicarbon unit sales in Europe partially offset by the expected decline in unit sales of the Omniscience heart valve which is an earlier generation product. We have focused our sales and marketing efforts on the Omnicarbon product line due to its superior clinical performance and market acceptance.

In fiscal years 2002 and 2001, the vast majority of our sales were denominated in U.S. dollars. Fluctuations in foreign currency exchange rates have not resulted in significant losses or gains on outstanding trade accounts receivable. All of our distributors are required to pay for products in U.S. dollars, other than our Japanese distributor, which pays in yen. We recognize that a strong U.S. dollar can adversely affect unit sales payable in currencies other than U.S. dollars for our foreign distributors.

**Gross Profit.** Gross profit as a percentage of net sales declined to 29.3 percent in the year ended April 30, 2002 from 37.0 percent in the prior year. We have expended considerable resources in developing our new carbon manufacturing process technologies utilized in manufacturing the Omnicarbon 4000 heart valve which is currently sold outside the U.S. market. Gross profit margins in the year ended April 30, 2002 were unfavorably impacted by non-recurring costs associated with these development activities. In particular, fiscal year 2002 cost of sales reflected higher Omnicarbon 4000 production costs during the first half of fiscal year 2002 when we were operating at lower production volumes due to the extensive development work we conducted in connection with our carbon manufacturing process. Our strategy is to obtain FDA approval of our proprietary

pyrolytic carbon manufacturing process in order to market the Omnicarbon 4000 in the U.S. Due to its lower manufacturing cost, we believe the Omnicarbon 4000 will generate significantly higher gross profit margins when sold in the U.S. than the Omnicarbon 3000 heart valve.

*Sales and Marketing.* Sales and marketing expenses in the year ended April 30, 2002 were \$2,089,104 or 70.1 percent of net sales compared to \$1,425,493 or 49.8 percent of net sales in the prior year. The increase in spending in fiscal year 2002 related to expanded Omnicarbon marketing efforts in the U.S. and international markets. Our overall marketing strategy is to promote the superior clinical results of the Omnicarbon heart valve and the technical strengths of our company in designing and manufacturing mechanical heart valves.

*General and Administrative.* General and administrative expenses for the year ended April 30, 2002 were \$1,817,159 or 60.9 percent of net sales compared to \$1,603,117 or 56.0 percent of net sales in the prior year. The increase was primarily attributable to increased legal and audit fees associated with operating as a public company, and salary and related expenses associated with strengthening the executive management staff.

*Engineering and Regulatory.* Engineering and regulatory expenses for the year ended April 30, 2002 were \$779,038 or 26.1 percent of net sales compared to \$965,472 or 33.7 percent of net sales in the prior year. The decrease in fiscal year 2002 spending was attributable to shifting priorities from new product development to installation of new equipment and processes for the production of the Omnicarbon 4000 heart valve.

*Other (Expense) Income.* Interest expense totaled \$241,197 in the year ended April 30, 2002 compared to \$207,314 in the prior year. The increase in fiscal year 2002 interest expense was attributable to maintaining a higher level of bank borrowings combined with the impact of the convertible bridge note financing in fiscal year 2002. Loss from the early extinguishment of convertible subordinated bridge notes of \$335,410 was reflected in fiscal year 2002.

*Income Tax Provision.* In light of our recent history of operating losses, we recorded a valuation allowance to fully offset our deferred tax assets in fiscal year 2000. We have continued to provide a full valuation allowance through fiscal year 2002 due to the inherent uncertainty of predicting the sufficiency of future taxable income necessary to realize our deferred tax assets.

*Loss from Operations.* As of April 30, 2002, we had an accumulated deficit of \$12,405,386. We have incurred losses in each of the last six fiscal years. Since 1994, we have invested in developing a bileaflet heart valve, a proprietary pyrolytic carbon coating process and obtaining premarket approval from the FDA to market our Omnicarbon 3000 heart valve in the U.S. Our strategy has been to invest in technology to better position ourselves competitively once FDA premarket approval was obtained. We expect cumulative net losses to continue at least through fiscal year 2003 because of anticipated spending necessary to market the Omnicarbon 3000 heart valve in the U.S. and to establish and maintain a strong marketing organization for domestic and foreign markets.

## **Liquidity and Capital Resources**

Cash and cash equivalents increased to \$2,781,675 at April 30, 2002, from \$111,977 at April 30, 2001. The increase in cash was attributable to completion of our initial public offering (IPO) in November 2001. Net cash used in operating activities was \$3,186,805 in the year ended April 30, 2002, and \$2,510,698 in the prior year.

Net cash used in operating activities increased \$676,107 due principally to the increase in our pre-tax loss in fiscal year 2002. Inventories increased \$188,084 in fiscal year 2002 and \$564,359 in fiscal year 2001. The increase in inventory in fiscal year 2002 and 2001 was related to the launch of the Omnicarbon 3000 in the U.S. market combined with anticipated growth in international sales.

Net cash used in investing activities was \$465,024 and \$516,344 for the years ended April 30, 2002 and 2001, respectively. We invested \$384,024 in property, plant, and equipment in the year ended April 30, 2002, compared to \$362,344 in the prior year. Our investment in property, plant, and equipment over the last two years related primarily to the development of our proprietary pyrolytic carbon manufacturing process. As described in Commitments and Contingent Liabilities, we loaned \$81,000 to UROPACE during fiscal year 2002 and \$154,000 in fiscal year 2001.

Net cash provided by financing activities was \$6,321,527 in the year ended April 30, 2002. We completed our IPO early in the third quarter of fiscal year 2002 which generated net proceeds of \$5,396,485. Other sources of cash from financing activities were our increased borrowings of \$1,570,000 on our line of credit and the net proceeds of \$438,885 from the sale of 10 percent convertible subordinated bridge notes described below. We used \$500,000 of funds generated through our IPO to

repay the bridge notes in the fourth quarter of fiscal year 2002 and \$475,000 to make principal payments on our bank line of credit. Net cash provided by financing activities was \$3,045,924 in fiscal year 2001. In the first quarter of fiscal year 2001, we obtained proceeds of \$2,925,000 from the issuance of 1,170,000 shares of our common stock in a private placement. In fiscal year 2001, we borrowed an additional \$2,315,000 on our bank line of credit partially offset by \$2,130,000 of principal payments on our bank line of credit.

From March 1992 through April 2002, our primary source of funding has been private sales of equity securities, which totaled \$9,775,704 in gross cash proceeds. We have also funded our operations through secured equipment financing term loans and equipment leases. In addition, we financed our operations since fiscal year 2000 through a bank line of credit secured by our real estate, tangible and intangible property and a guarantee by a principal shareholder. This line of credit will expire in November 2002. Amounts borrowed under this line of credit generally bear interest at the prime rate. As of April 30, 2002, we had borrowed the maximum amount available of \$2,500,000 under this line of credit.

As part of our credit agreement with Associated Bank Minnesota, we were required to maintain a minimum tangible net worth of not less than \$3,000,000, measured as of the last day of each fiscal quarter. At April 30, 2001, we failed to comply with the minimum tangible net worth covenant. On August 24, 2001, Associated Bank Minnesota waived such covenant defaults, and we amended our credit agreement, which now provides that we must maintain a minimum tangible net worth of not less than \$1,000,000, measured as of the last day of each calendar month. We were in compliance with our debt covenants as of April 30, 2002.

In August 2001, we sold \$500,000 principal amount of 10% convertible subordinated bridge notes due August 2002, along with five-year warrants to purchase 500,000 shares of common stock at an exercise price of \$6.50 per share. The unsecured notes were convertible into shares of our common stock at any time before repayment at a price of \$4.50 per share. We repaid the convertible subordinated bridge notes in full in the fourth quarter of fiscal year 2002.

We expect to continue developing our business and to build market share in the U.S. now that we have FDA premarket approval of our Omnicarbon 3000 heart valve for sales in the U.S. These activities will require significant expenditures to develop, train and supply marketing materials to our independent sales representatives and to build our sales and marketing infrastructure. As a result, we anticipate that our sales and marketing and general and administrative expenses will continue to constitute a material use of our cash resources. Although we have no commitment for these expenditures, we currently anticipate spending between \$4,900,000 and \$5,600,000 in fiscal year 2003. In addition, we project capital expenditures of approximately \$250,000 to \$350,000 for fiscal year 2003 to increase manufacturing capacity in certain functions and make necessary improvements to our corporate facility. The actual amounts and timing of our capital expenditures will vary depending upon the speed at which we are able to expand our distribution capability in domestic and international markets and the availability of financing as described below.

We expect that our operating losses and negative operating cash flow will continue in fiscal years 2003 and 2004 as we expand our manufacturing capabilities, continue increasing our corporate staff to support the U.S. roll-out of our Omnicarbon 3000 heart valve, and add marketing programs domestically and internationally to build awareness of and create demand for our Omnicarbon heart valves. We will require additional financing in fiscal year 2003. We anticipate that we will need to raise between \$3,000,000 and \$4,000,000 of additional equity or debt financing to fund operations and working capital requirements for the next 12 to 18 months. We expect to face substantial difficulty in raising funds in the current market environment and we have no commitments at this time to provide the required financing. We will seek to refinance our bank debt before November 2002 to give us additional borrowing capacity and flexibility in funding the growth of our business. Our capital requirements may vary depending upon the timing and the success of the implementation of our business plan, regulatory, technological and competitive developments, or if:

- our manufacturing and development costs or projections prove to be inaccurate,
- we determine to license or develop additional technologies,
- we experience substantial delays in obtaining FDA clearance of our proprietary carbon coating process for heart valves sold in the U.S. market, or
- we make acquisitions.

We cannot assure you that we will be able to raise sufficient capital on terms that we consider acceptable, or at all. If we are unable to obtain adequate funds on acceptable terms, our ability to fund the expansion of our business or respond to

competitive pressures would be significantly impaired. We also would be required to revise our business plans and reduce operating expenditures. In the event that we are unable to refinance our revolving line of credit and obtain funds by the end of calendar year 2002, we will be required to significantly revise our business plans and substantially reduce our operating expenditures.

### **Commitments and Contingent Liabilities**

*Sulzer Carbomedics.* In July 1998, we entered into a three-year supply agreement with Sulzer Carbomedics, the source of certain raw material components used in the manufacture of our Omnicarbon 3000 heart valves. The supply agreement was extended for an additional two years in March 2001. The agreement provides that we purchase a minimum number of raw material units each calendar year through 2003. Under the terms of the agreement, we are required to compensate Sulzer Carbomedics for any purchase shortfalls up to a maximum of \$200,000 per year. We have not met the minimum purchase requirements for the past three calendar years. In addition, we do not believe we will meet the minimum purchase requirement for calendar year 2002. As a result, we expensed \$148,991 in fiscal year 2002, and \$108,174 in fiscal year 2001 related to these purchase shortfalls. These charges were reflected in cost of goods sold. Future purchase shortfalls could adversely affect our ongoing relationship with Sulzer Carbomedics.

*UROPACE.* In July 1995, we established a wholly-owned subsidiary, UROPACE, Inc., to commercialize technology for treating female urinary incontinence. On November 1, 2000, we completed the spin-off of UROPACE to our existing shareholders. The separation was effected by transferring from our company to UROPACE all assets, tangible and intangible, relating to the development of female urinary incontinence technology. Our shareholders of record on September 15, 2000 received one share of common stock of UROPACE for each 6.882 shares of our common stock they held on that date. The assets transferred to UROPACE had no book value at November 1, 2000, and the operations of UROPACE before the spin-off had no revenues and minimal expenses during fiscal year 2000 and fiscal year 2001. As a part of this spin-off, we agreed to loan UROPACE up to \$356,250 at a variable interest rate. Principal and interest on the note will be payable in installments equal to 5 percent of UROPACE's future annual net sales until the note and interest is paid in full. At April 30, 2002, we had loaned UROPACE \$235,000. Due to the development stage of UROPACE and the uncertainty associated with the collection of these borrowings, we have recorded an allowance for the entire balance of the loan, with the corresponding expense included in other (expense) income in the Consolidated Statement of Operations.

*Bank Line of Credit.* Since fiscal year 2000, we have financed our operations in part through a bank line of credit secured by our real estate, tangible and intangible property and a guarantee by a principal shareholder. This line of credit will expire in November 2002. Amounts borrowed under this line of credit generally bear interest at the prime rate. As of April 30, 2002, we had borrowed the maximum amount available of \$2,500,000 under this line of credit.

As part of our revolving credit agreement with Associated Bank Minnesota, we were formerly required to maintain a minimum tangible net worth of not less than \$3,000,000, measured as of the last day of each fiscal quarter. At April 30, 2001, we failed to comply with the minimum tangible net worth covenant. On August 24, 2001, Associated Bank Minnesota waived such covenant defaults, and we amended our credit agreement, which now provides that we must maintain a minimum tangible net worth of not less than \$1,000,000, measured as of the last day of each calendar month. With the net proceeds from our November 2001 IPO, we met our minimum tangible net worth requirement through April 30, 2002. As of April 30, 2002, we had fully utilized our line of credit.

As of April 30, 2002, we were in compliance with all covenants or other requirements set forth in our credit agreement. We do not have any rating downgrade triggers that would accelerate the maturity dates of our debt. A downgrade in our credit rating could adversely affect our ability to renew existing, or obtain access to new, credit facilities in the future and could increase the cost of such facilities.

*Dakota Electric Association.* We were indebted to Dakota Electric Association in the principal amount of \$165,983. Payments are due in monthly installments through May 2009, with interest at 5.75 percent, collateralized by our lighting equipment and rooftop air-conditioning units.

*Dakota County.* We owe Dakota County for special land assessments with principal and interest due at 8 percent in semi-annual installments through May 2010.

*Operating and Capital Leases.* We lease certain manufacturing equipment under various operating and capital leases. The operating leases expire at various dates through fiscal year 2003. The capital lease terms extend into fiscal year 2004 with implicit interest rates ranging from 6.9 to 16.2 percent. The capital leases are collateralized by the underlying equipment with a total original cost of \$322,733.

*Clinical Studies.* We entered into an agreement with several large non-U.S. hospitals to conduct clinical studies regarding certain aspects of our Omnicarbon heart valve's clinical performance. The agreement runs through fiscal year 2006. In general, recipients of clinical study payments are required to purchase our products in order to complete their studies.

*Consulting.* In November 2001, we entered into a separation agreement and release with Adel A. Mikhail, Ph.D., who was our founder and served as our President and Chief Executive Officer from March 1992 until June 15, 2001, when he retired. Dr. Mikhail continues to serve as Chairman of our Board of Directors. As part of the agreement, we agreed to retain Dr. Mikhail as an independent consultant for a period of two years. Dr. Mikhail receives a \$6,000 per month retainer. The agreement expires in June 2003.

#### Summary of Contractual Obligations

	TOTAL	Payments Due By Period		
		Less than One Year	Two to Three Years	Four or More Years
Sulzer Carbomedics.....	\$ 200,000	\$ 200,000	\$	\$
UROPACE Loan.....	121,250	121,250		
Bank Line of Credit.....	2,500,000	2,500,000		
Dakota Electric Association (1).....	202,469	28,584	57,168	116,717
Dakota County (1).....	255,360	39,360	72,960	143,040
Operating Leases.....	19,742	19,742		
Capital Leases (1).....	112,936	67,480	45,456	
Clinical Studies.....	422,380	143,762	198,247	80,371
Consulting.....	81,000	72,000	9,000	
<b>TOTAL CONTRACTUAL OBLIGATIONS .....</b>	<b>\$ 3,915,137</b>	<b>\$ 3,192,178</b>	<b>\$ 382,831</b>	<b>\$ 340,128</b>

(1) Future payments include interest due.

#### Recent Accounting Pronouncements

In June 2001, the FASB issued SFAS No. 141, "Business Combinations," which addresses accounting and financial reporting for business combinations. Also in June 2001, the FASB issued SFAS No. 142, "Goodwill and Other Intangible Assets," which addresses how intangible assets acquired individually or with a group of other assets, except for those acquired in a business combination, should be accounted for in financial statements upon their acquisition and how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. Both of these statements are effective in their entirety for our company on May 1, 2002. The adoption of these statements will not have a material impact on our current financial position or our results of operations.

In August 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 144, "Accounting for the Disposal of Long-Lived Assets," which addresses accounting and financial reporting for long-lived assets. This statement is effective for us on May 1, 2002. The adoption of this statement is not expected to have a material impact on our financial position or results of operations.

In May 2002, the FASB issued SFAS No. 145, "Rescission of SFAS Nos. 4, 44, and 64, Amendments to SFAS No. 13, and Technical Corrections as of April 2002." The new statement amends existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. SFAS No. 145 was adopted by us effective May 1, 2001. The adoption of SFAS No. 145 required the classification of the loss on early extinguishment of convertible subordinated bridge notes as a component of net loss from recurring operations for fiscal year 2002 versus being classified as an extraordinary item.

#### Qualitative and Quantitative Disclosures about Market Risk

We develop our products in the U.S. and market our products globally. Because we continue to derive our revenue primarily from sources outside of the U.S., our financial results could be affected by many factors, such as changes in currency exchange rates or weak economic conditions in foreign markets. Substantially all of our sales are denominated in U.S. dollars. A strengthening of the U.S. dollar could make our products less competitive in foreign markets. We do not currently participate in any currency hedging activities to mitigate this risk. We intend to assess the need to use financial instruments to hedge our exchange rate exposure on an ongoing basis. Our interest income and expenses are sensitive to changes in the general level of U.S. interest rates, particularly since our investments are in short-term instruments and our long-term debt and

revolving line of credit require interest payments calculated at variable rates. Based on the current nature and levels of our investments and debt, however, we believe that we currently have no material market risk exposure.

Our general investing policy is to limit market and credit risk and the risk of principal loss. All liquid investments with original maturities of three months or less are considered to be cash equivalents.

### **Cautionary Statement**

*MedicalCV, Inc., or persons acting on our behalf, or outside reviewers retained by us making statements on our behalf, or underwriters of our securities, from time to time, may make, in writing or orally, "forward-looking statements" as defined under the Private Securities Litigation Reform Act of 1995. This Cautionary Statement, when used in conjunction with an identified forward-looking statement, is for the purpose of qualifying for the "safe harbor" provisions of the Litigation Reform Act and is intended to be a readily available written document that contains factors which could cause results to differ materially from such forward-looking statements. These factors are in addition to any other cautionary statements, written or oral, which may be made, or referred to, in connection with any such forward-looking statement.*

*The following matters, among others, may have a material adverse effect on our business, financial condition, liquidity, results of operations or prospects, financial or otherwise. Reference to this Cautionary Statement in the context of a forward-looking statement or statements shall be deemed to be a statement that any one or more of the following factors may cause actual results to differ materially from those in such forward-looking statement or statements.*

### **Risks related to our business**

**We may be unable to fund our significant future capital needs, and we may need additional funds sooner than anticipated.** Based on our current rate of expenditures, anticipated net sales and current sales and marketing plans, we estimate that we will need to raise between \$3,000,000 and \$4,000,000 of additional equity or debt financing to fund operations and working capital requirements for the next 12 to 18 months. We expect to face substantial difficulty in raising funds in the current market environment and we have no commitments at this time to provide the required financing. We seek to refinance our bank debt before November 2002 to give us additional borrowing capacity and flexibility in funding the growth of our business. The timing and amount of our future capital requirements will depend on a number of factors, including:

- the extent to which our Omnicarbon 3000 heart valve gains market acceptance in the U.S.;
- costs of manufacturing and marketing;
- potential reductions in heart valve pricing by our competitors;
- costs of licensing and acquiring new products and technologies;
- time and costs involved in obtaining regulatory clearance for our pyrolytic carbon coating process for sales in the U.S. of our Omnicarbon 4000 heart valve and other unanticipated regulatory costs;
- costs involved in filing, prosecuting and enforcing patents or defending against any patent infringement claims;
- competing technological and market developments; and
- progress and cost of clinical trials for new products.

We will require additional capital to support future operations, to complete the development of products and to manufacture and market any products resulting from current development projects. We cannot assure you that such additional financing will be available on acceptable terms, or at all. If funds are raised by issuing additional equity securities, our then existing shareholders will experience further dilution. If we are unable to obtain additional funds as needed, we may not be able to:

- develop or enhance our products,
- gain market share in the U.S., or
- respond to competitive pressures or unanticipated requirements.

In the event that we are unable to refinance our revolving line of credit and obtain funds by the end of calendar year 2002, we will be required to significantly revise our business plans and substantially reduce our operating expenditures.

**We anticipate future losses and negative cash flows, which may limit or delay our ability to become profitable.**

We have incurred losses in each of the last six fiscal years. We had net losses of \$4,297,665 for the fiscal year ended April 30, 2002 and \$3,238,829 for the fiscal year ended April 30, 2001. As of April 30, 2002, we had an accumulated deficit of \$12,405,386. If we fail to obtain financing when required, we may not be able to develop or enhance our products, gain market share in the U.S. or respond to competitive pressures or unanticipated requirements, which could seriously harm our business, financial position and results of operations. We expect to incur additional net losses until we are able to generate and sustain substantially higher revenues while maintaining reasonable expense levels, both of which involve uncertainty. We also must continue to make significant expenditures on sales and marketing in connection with our heart valves. We cannot assure you that our revenues will grow in future periods or that we will ever become profitable. If we do achieve profitability, we cannot assure you that we would be able to sustain or increase profitability on a quarterly or annual basis in the future. In addition, the report of our independent accountants for fiscal year 2002 includes an explanatory paragraph expressing doubt about our ability to continue as a going concern.

**We rely upon sales of our Omnicarbon heart valves for substantially all of our revenue.** Our results of operations materially depend on the success of the Omnicarbon 3000 and 4000 heart valves, which accounted for substantially all of our operating revenue for the fiscal years ended April 30, 2002 and April 30, 2001. A significant reduction in sales of Omnicarbon heart valves for any reason, including the introduction of additional competing products, would have a material adverse effect on us. If we develop additional products, we would need to obtain regulatory approval before we could sell them. Given the time-consuming nature of the regulatory clearance process, we do not expect to be able to sell such additional products in the foreseeable future. We also anticipate that research and development and clinical and regulatory expenses will continue to rise in future periods.

**We cannot assure you that our heart valves will gain physician acceptance.** A limited number of cardiovascular surgeons and cardiologists can influence medical device selection and purchase decisions for a large portion of the target cardiovascular surgery patient population. We cannot assure you that our Omnicarbon heart valves, or any of the products that we may develop, will gain any significant degree of physician acceptance, or that users will accept these products as preferable to alternative products or methods of treatment. Physician acceptance of our Omnicarbon heart valves will depend upon our ability to demonstrate the clinical advantages of lower complication rates and cost-effectiveness of Omnicarbon heart valves when compared to other prosthetic heart valves. Negative publicity involving Omnicarbon heart valves or other prosthetic heart valves could adversely affect the overall acceptance of Omnicarbon heart valves. Further, because Omnicarbon heart valves are monoleaflet heart valves, we must overcome in the U.S. and in other markets a preference for bileaflet heart valves, which are marketed by most major manufacturers of mechanical heart valves. Any of the foregoing factors, among others, could limit or detract from physician acceptance of our product and have a negative effect on our business, financial condition, operating results and cash flows.

**Because we do not have FDA clearance to manufacture our Omnicarbon 3000 heart valves using our own pyrolytic carbon process for sale in the U.S., we depend upon a third party supplier for critical components.** We market our Omnicarbon 3000 heart valves, which we have now begun to sell in the U.S. and Japan, with pyrolytic carbon components produced by Sulzer Carbomedics, a third party supplier which sells competing heart valves. We have a supply contract that requires us to purchase such components for use in the Omnicarbon 3000 heart valve solely from Sulzer Carbomedics until December 2003. Given the absence of FDA-cleared alternative sources for pyrolytic carbon components for our Omnicarbon 3000 heart valves, any disruption or termination of our supply contract, or our failure to extend it, if necessary, would have a material adverse effect on our continued ability to sell Omnicarbon 3000 heart valves. Future purchase shortfalls could adversely affect our ongoing relationship with Sulzer Carbomedics. Further, we cannot assure you that we will be able to obtain FDA clearance to manufacture Omnicarbon heart valves for sale in the U.S. using our own pyrolytic carbon process. Our future success will depend, in part, on obtaining FDA clearance to manufacture carbon components for heart valves for sale in the U.S.



**We may need to fund multiple research studies throughout the lifecycle of each of our products, providing statistically significant scientific data to regulatory agencies and cost effectiveness data to third party payers.** The FDA, foreign regulatory agencies and third party health care payers may require scientific clinical outcomes data and cost effectiveness data. We will need to provide this data throughout our products' lifecycles. Payers and governmental agencies may change the frequency and breadth of clinical research required, potentially significantly increasing our costs. Without adequate positive outcomes data that demonstrate advantages from the use of our Omnicarbon heart valves, we may not achieve any significant market penetration. We cannot assure you that our outcomes data will be adequate to meet present or future medical device utility requirements. If our outcomes data does not meet such requirements, we may be unable to sell our products or obtain third party reimbursement for the costs of our products.

**Intense competition in the prosthetic heart valve industry could prevent us from successfully marketing our products or render our products obsolete.** We compete in mature, highly competitive markets in which many of our competitors have well-known and established products. To compete successfully in these markets, we must maintain competitive pricing and demonstrate the advantages of our Omnicarbon heart valves in terms of post-surgical complications. Several companies are currently pursuing new mechanical heart valve designs, blood compatible coatings for mechanical heart valves, longer lasting tissue heart valves and surgical alternatives to implanting prosthetic heart valves. It is possible that technological advances by our competitors, or advances in surgical procedures that delay the need for replacing heart valves, could render our Omnicarbon heart valves noncompetitive or obsolete.

Our primary competitors, St. Jude Medical, Inc., Medtronic, Inc. and Sulzer Carbomedics, dominate the market and control most of the mechanical heart valve market worldwide. Our competitors have extensive clinical data demonstrating the performance of their heart valves and internal carbon manufacturing capabilities. The companies with which we compete have many additional competitive advantages over us, including:

- greater name recognition and product market acceptance;
- more established physician relationships;
- broader product lines;
- greater distribution capabilities;
- greater regulatory compliance capabilities;
- larger marketing, research and development staffs and facilities; and
- greater financial resources.

We cannot assure you that we will be able to compete against such competitors or their products.

**Our future results depend upon the strength of the mechanical heart valve market.** Our business could suffer if the use of mechanical heart valves declines. In recent years, there has been an increase in the number of tissue heart valves used. We believe that improvements in tissue heart valve longevity and an increase in the average age of heart valve patients have contributed to the recent increase in the use of tissue heart valves. If the use of mechanical heart valves declines, it could materially adversely affect our business, financial condition, operating results and cash flows.

**The small number of distributors operating in foreign markets who currently generate substantially all of our revenues pose a concentration of credit risk and could leave us at any time, impairing our business.** Substantially all of our sales originate from eight distributors who market our Omnicarbon 4000 heart valves in Europe, South Asia, the Middle East and the Far East. Because we do not control the amount or timing of the resources such parties allocate to sales of our product, any revenues we derive from such relationships depend upon the efforts of such distributors. If we could not locate a replacement on a timely basis, the loss of an international distributor could adversely affect us.

Certain of our significant international distributors are affiliates of our company. During our fiscal year ended April 30, 2002, such affiliates made net purchases of product from our company equal to approximately 48.6 percent of our net sales. During our fiscal year ended April 30, 2001, such affiliates made net purchases of product from our company equal to approximately 45.5 percent of our net sales. Obligations to us from our distributors are unsecured. Such affiliates could fail to

pay receivables or cease distributing our products at any time, thereby materially and adversely affecting our business, financial condition, operating results and cash flows.

**We depend upon sales outside the U.S., which are subject to a number of risks that could harm our ability to successfully commercialize our product and could harm our business.** We face several risks as a result of doing business in foreign markets, including:

- unforeseen changes in regulatory requirements and government health programs;
- potentially adverse tax consequences;
- political and economic instability; and
- greater difficulty in collecting payments from product sales.

In addition, the value of the U.S. dollar in relation to other currencies may also harm our sales to customers outside the U.S. because we require substantially all of our customers to pay for our products in U.S. currency.

**Substantial government regulation in the U.S. and abroad may restrict our ability to sell our heart valves.** The FDA and comparable regulatory authorities in foreign countries extensively and rigorously regulate our products, product development activities and manufacturing processes. In the U.S., the FDA regulates the introduction of medical devices as well as the manufacturing, labeling and record-keeping procedures for such products. We are required to:

- obtain clearance before we can market and sell medical devices;
- satisfy content requirements applicable to our labeling, sales and promotional materials;
- comply with manufacturing and reporting requirements; and
- undergo rigorous inspections.

The process of obtaining marketing clearance for new medical devices from the FDA can be costly and time consuming. For example, the premarket clearance process, which our medical devices must undergo, can require numerous years to complete. Although we recently obtained FDA clearance for our Omnicarbon 3000 heart valve, we cannot assure you that our future products will obtain FDA clearance on a timely basis, or at all. Our products must also comply with laws and regulations of foreign countries in which we market such products. In general, the extent and complexity of medical device regulation is increasing worldwide. This trend may continue, and the cost and time required to obtain marketing clearance in any given country may increase as a result. We cannot assure you that our products will obtain any necessary foreign clearances on a timely basis, or at all.

**Once medical devices are cleared for sale, regulatory authorities may still limit the use of such products, restrict sales to certain models or sizes, prevent the sale or manufacture of such products or require a recall or withdrawal of such products from the marketplace.** Following initial clearance from regulatory authorities, we continue to be subject to extensive regulatory requirements. Government authorities can withdraw marketing clearance due to our failure to comply with regulatory standards or due to the occurrence of unforeseen problems following initial clearance. Ongoing regulatory requirements are wide-ranging and govern, among other things:

- annual inspections to retain CE mark for sale of products in the European Union;
- product manufacturing;
- annual inspections to retain ISO certification of our quality system;
- supplier substitution;
- product changes;

- process modifications;
- medical device reporting; and
- product sales and distribution.

The FDA and various government agencies inspect our facilities from time to time to determine whether we are in compliance with applicable laws and regulations. If we fail to comply or maintain compliance with medical device laws or regulations, regulatory authorities may fine us and bar us from selling our products. If the FDA believes we are not in compliance with such laws or regulations, it can:

- seize our products;
- require a recall;
- withdraw previously granted market clearances;
- implement procedures to stop future violations; and/or
- seek civil and criminal penalties against us.

**The uncertainty of third party reimbursements and possible health care reforms may adversely affect us.** Our ability to market products successfully in the U.S. will depend in part on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health insurers, health maintenance organizations and other third party payers. Payers increasingly challenge the need for, and prices of, medical products and services. Payers may deny reimbursement for procedures that they deem experimental or for devices used in ways other than as cleared by the FDA or stated in their indications for use. With respect to our products, some payers could deny coverage until the devices become generally accepted by the medical profession. The inability of hospitals and other providers to obtain reimbursement from third party payers for our products would have a material adverse impact on our business, financial condition, operating results and cash flows.

Health care reform may also impact sales of new products in the U.S. Reforms may include:

- mandated basic health care benefits;
- controls on health care spending through limiting the growth of private health insurance premiums and Medicare and Medicaid spending; and
- fundamental changes to the health care delivery system.

We anticipate that Congress and state legislatures will continue to review and assess alternative health care delivery systems and payment methodologies, and that public debate of these issues will likely continue in the future. Due to uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation, we cannot predict which, if any, of such reform proposals will be adopted, when they may be adopted or what impact they may have on our ability to market our current and future products. Laws resulting from such reform initiatives could adversely impact our business, financial condition, operating results and cash flows.

**Despite our efforts to protect our proprietary rights, unauthorized parties may attempt to use information that we regard as proprietary. We also run the risk of infringing the proprietary rights of third parties.** We do not have patent protection for the design of our Omnicarbon heart valves. We rely upon a combination of trade secrets, know-how and confidentiality agreements to protect the proprietary aspects of our technology, including aspects of manufacturing. We have patent applications filed for the pyrolytic carbon coating process used in our Omnicarbon 4000 heart valve. We have patents for our bileaflet mechanical heart valve project which is currently under development. We expect to seek patent protection for additional products in the future. Our success will depend, in part, on our ability to protect our products and to manufacture and sell them without infringing the rights of third parties. The validity and breadth of claims covered in medical technology patents involve complex legal and factual questions and, therefore, are highly uncertain. In addition, the laws of many countries do not protect our proprietary rights to as great an extent as do the laws of the U.S. We cannot assure you that:

- any pending patent applications or any future patent applications will result in the issuance of patents;
- the scope of any patent protection will be effective to exclude competitors or to provide competitive advantages to us;
- we will be able to commercially exploit any issued patents before they expire;
- any of our patents will be held valid if subsequently challenged;
- others will not claim rights in, or ownership of, the patents and other proprietary rights we hold;
- our products and processes will not infringe, or be alleged to infringe, the proprietary rights of others; or
- we will be able to protect meaningful rights in proprietary technology over which we do not hold patents.

Furthermore, we cannot assure you that others have not developed or will not develop products which may duplicate any of our products or manufacturing processes, or that others will not design around our patents. Other parties may independently develop or otherwise acquire substantially equivalent techniques, gain access to our proprietary technology or disclose such technology. In addition, whether or not we obtain additional patents, others may hold or receive patents covering components of products we independently develop in the future. We cannot assure you that third parties will not claim infringement by us, and seek substantial damages, with respect to current or future products. If we were to become involved in a dispute regarding intellectual property, whether ours or that of another company, we may be involved in legal proceedings. Any such claims, with or without merit, could be time-consuming, result in costly litigation, cause product shipment delays and require us to:

- cease manufacturing and selling our product, which would seriously harm us;
- enter into royalty or licensing agreements; or
- design commercially acceptable non-infringing alternative products.

We cannot assure you that we would be able to obtain royalty or licensing agreements, if required, on terms acceptable to us or at all, or that we would be able to develop commercially acceptable non-infringing alternative products. Our failure to do so could have a material adverse effect upon our business, financial condition, operating results and cash flows.

**If patients allege that the use of Omnicarbon heart valves adversely affected them, we may face substantial product liability claims.** Substantial product liability litigation exists within the medical device industry. Mechanical heart valves are life-sustaining devices, and their failure may result in patient death. We have had product liability claims in the past, which have been resolved without material financial cost to us. We cannot assure you, however, that future product liability claims will not exceed the limits of our insurance coverage or that such insurance will continue to be available on commercially reasonable terms, or at all. Consequently, a product liability claim or other claim with respect to uninsured liabilities, or in excess of insured liabilities, could have a material adverse effect on our business, financial condition, operating results and cash flows. In addition, adverse publicity resulting from product liability litigation may materially adversely affect us regardless of whether the claims are valid or whether we are liable. These claims may divert our financial and management resources that would otherwise be used to benefit the future performance of our operations.

**Key employees could leave our company at any time, impairing our development and profitability.** We depend heavily on the technical knowledge and industry expertise of our management team and our founder and former chief executive officer, Adel A. Mikhail, Ph.D., with whom we have a two-year consulting agreement. The development and execution of our business plan depends upon these individuals. We do not have employment agreements with most of our key employees. The departure of key people could adversely affect our business, financial condition, operating results and cash flows.

**We may be unable to recruit, motivate and retain qualified employees.** Our success depends upon our ability to attract, motivate and retain a sufficient number of qualified employees, including those who concentrate in research and development, sales, marketing and manufacturing, to keep pace with our product development schedules. Even though we

have not experienced shortages of qualified people to date, qualified individuals needed to fill these positions could be in short supply in our market. Our inability to recruit, motivate and retain such individuals may delay the planned launch of new products or result in high employee turnover, either of which could have a material adverse effect on our business, financial condition, operating results and cash flows. Additionally, competition for qualified employees could require us to pay higher wages and provide additional benefits to attract sufficient employees.

**We may be unable to collect on our loan to UROPACE, Inc.** In July 1995, we established a wholly-owned subsidiary called UROPACE, Inc. On November 1, 2000, we completed a spin-off of UROPACE to our existing shareholders. As part of this spin-off, we agreed to loan UROPACE up to \$356,250 at a variable interest rate. As of April 30, 2002, we had loaned UROPACE \$235,000. Principal and interest on the note is payable in installments equal to 5 percent of UROPACE's future annual net sales until the note is paid in full. Due to the development stage of UROPACE, it is uncertain whether we will be able to collect on this loan. For financial reporting purposes, we have recorded an allowance for the entire balance of the loan at April 30, 2002.

### ***Risks related to our securities***

**Fluctuations in our operating results may result in decreases in the price of our securities.** Our operating results have and will continue to fluctuate significantly because of several factors, including the timing of FDA clearance, government policies regarding payment for our products and new technology. Consequently, our operating results may fall below the expectations of public market analysts and investors. In that event, the price of our securities would likely decrease.

**No public market exists for our common stock or Class A Warrants, and an active market may not develop for our units.** No public market exists for our common stock or Class A Warrants. Such a market may not exist until at least May 20, 2003, when the unit components may be traded separately. We cannot assure you that an active market for such securities will develop in the future or that an active market for our units will develop. Before our initial public offering, there was no public market for our units. As a result, we arbitrarily established the offering price for the units and the exercise price of the Class A Warrants through negotiations with our underwriter. Such prices were not based upon our assets, earnings history or book value.

**If we do not maintain our Nasdaq listing, you may have difficulty reselling your units.** We will need to maintain certain financial and corporate governance qualifications to keep our units listed on The Nasdaq SmallCap Market and to obtain listing for our common stock and Class A Warrants. We cannot assure you that we will at all times meet the criteria for continued or initial listing. If we fail to maintain such qualifications, including a minimum bid price for our units of \$1.00, our units may be delisted and our common stock and Class A Warrants may not become listed. In the event of delisting or failure to list, trading, if any, would be conducted in the over-the-counter markets in the so-called "pink sheets" or the National Association of Securities Dealers, Inc. "Electronic Bulletin Board." At that point, our securities would become subject to the SEC's "penny stock rules." The penny stock rules would impose additional requirements on broker-dealers who effect trades in our securities other than trades with their established customers and accredited investors. Consequently, the delisting or failure to list our securities and the applicability of the penny stock rules may adversely affect the ability of broker-dealers to sell our securities, which may adversely affect your ability to resell our securities. If any of these events take place, you may not be able to sell as many securities as you desire, you may experience delays in the execution of your transactions and our securities may trade at a lower market price than they otherwise would.

**Our existing shareholders have significant control, which could reduce your ability to receive a premium for your securities through a change in control.** Officers and directors of our company beneficially own 38.6 percent of our common stock. As a result, they may be able to control our company and direct our affairs, including the election of directors and approval of significant corporate transactions. This concentration of ownership could also delay, defer or prevent a change in control of our company, and make some transactions more difficult or impossible without their support. These transactions might include proxy contests, tender offers, open market purchase programs or other share purchases that could give our shareholders the opportunity to realize a premium over the then prevailing market price of our securities. As a result, this concentration of ownership could depress the price of our securities.

**Minnesota law and our ability to issue preferred stock could deter a take-over or acquisition of our company.** Our articles of incorporation authorize the issuance of shares of preferred stock. Our board of directors, without any action by our shareholders, is authorized to designate and issue the preferred stock in such classes or series as it deems appropriate and establish the rights and privileges of such shares, including liquidation and voting rights. Our ability to designate and issue preferred stock having preferential rights over our common stock could adversely affect the voting power and other rights of holders of common stock, should we determine to issue preferred stock. We are also subject to the Minnesota Business Corporation Act, which includes provisions that limit the voting rights of persons acquiring specified percentages of shares of

an issuing public corporation in a "control share acquisition" and restrict "business combinations" between issuing public corporations and specified persons acquiring their securities. Our ability to issue preferred stock and the application of the provisions of Minnesota law discussed above could impede or deter another company from making a tender offer or other proposal to take us over.

**We may redeem the Class A Warrants at a nominal price.** We may redeem the Class A Warrants at \$0.01 per warrant at any time once they become exercisable, upon ten business days' notice, if the closing price of our common stock or units exceeds \$8.50, subject to customary anti-dilution adjustments, for any ten consecutive trading days before such notice. If we redeem the Class A Warrants, you will lose your right to exercise the Class A Warrants except during the ten business day notice period. Our redemption of the Class A Warrants could force you to exercise the Class A Warrants at a time when it may be disadvantageous for you to do so, to sell the Class A Warrants at the then current market price or to accept the redemption price, which could be substantially less than the market value of the Class A Warrants at the time of redemption.

**If we do not maintain an effective prospectus, you will be unable to exercise your Class A Warrants.** You will be able to exercise the Class A Warrants, and we will be able to issue shares to you upon such exercise, only if a current prospectus relating to the shares underlying the Class A Warrants is then in effect and only if such securities are qualified for sale or exempt from qualification under the applicable securities laws of the state in which you reside. Although we cannot assure you that we will actually be able to do so, we will use our best efforts to:

- maintain the effectiveness of a current prospectus covering the shares underlying the Class A Warrants, and
- maintain the registration of such shares under the securities laws of the states in which we initially qualified the units for sale in our initial public offering.

**We have broad discretion to use the proceeds from our initial public offering for purposes with which you may not agree, and we may not be successful in investing the proceeds.** We plan to use the proceeds from our initial public offering for general corporate purposes including, but not limited to, marketing, developing various medical devices and, potentially, licensing technology from third parties. The amounts actually expended for the above purposes may vary significantly depending upon a number of factors. Therefore, we will have broad discretion as to how we will spend the proceeds. Shareholders may not agree with the ways in which we use the proceeds and our management may not make the best use of the proceeds. We cannot predict whether our management's investment of the proceeds will yield a favorable, or any, return.

## **ITEM 7 FINANCIAL STATEMENTS**

### **INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

#### **MedicalCV, Inc.**

Report of Independent Accountants

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Notes Consolidated to Financial Statements

## **Report of Independent Accountants**

To the Board of Directors and Shareholders of MedicalCV, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of changes in shareholders' equity and of cash flows present fairly, in all material respects, the financial position of MedicalCV, Inc. at April 30, 2002 and 2001, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has sustained losses and negative cash flows from operations in recent years and has insufficient funds to meet the requirements of its revolving credit facility, which matures November 2002, and finance its working capital and capital expenditure needs, which raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP  
PricewaterhouseCoopers LLP  
June 6, 2002

**MedicalCV, Inc.**  
**Consolidated Balance Sheet**

	April 30,	
	2002	2001
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents.....	\$ 2,781,675	\$ 111,977
Trade accounts receivable, net .....	1,258,616	1,125,560
Inventories.....	2,322,535	2,172,035
Prepaid expenses and other assets .....	78,993	127,354
Total current assets .....	<u>6,441,819</u>	<u>3,536,926</u>
Property, plant and equipment, net.....	1,575,153	1,446,382
Deferred financing costs, net.....	72,860	233,936
Other assets.....	1,394	1,394
Total assets.....	<u>\$ 8,091,226</u>	<u>\$ 5,218,638</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of long-term debt.....	\$ 2,542,460	\$ 42,460
Current portion of capital lease obligations.....	59,854	61,552
Accounts payable.....	589,520	511,340
Accrued expenses .....	491,760	314,524
Total current liabilities .....	<u>3,683,594</u>	<u>929,876</u>
Long-term debt, less current portion.....	339,523	1,786,987
Capital lease obligations, less current portion .....	42,069	72,504
Total liabilities.....	<u>4,065,186</u>	<u>2,789,367</u>
Commitments and contingencies (Notes 5, 9 and 11).....		
Shareholders' equity:		
Preferred stock, \$.01 par value; 5,000,000 shares authorized; no shares issued and outstanding .....	—	—
Common stock, \$.01 par value; 95,000,000 shares authorized; 7,843,834 and 6,343,834 shares issued and outstanding, respectively.....	78,438	63,438
Additional paid-in capital.....	16,362,050	10,490,378
Deferred stock-based compensation .....	(9,062)	(16,824)
Accumulated deficit.....	(12,405,386)	(8,107,721)
Total shareholders' equity.....	<u>4,026,040</u>	<u>2,429,271</u>
Total liabilities and shareholders' equity .....	<u>\$ 8,091,226</u>	<u>\$ 5,218,638</u>

The accompanying notes are an integral part of these financial statements.



**MedicalCV, Inc.**  
**Consolidated Statement of Operations**

	Year ended April 30,	
	2002	2001
Net sales.....	\$ 2,982,198	\$ 2,863,440
Cost of goods sold.....	<u>2,109,453</u>	<u>1,804,278</u>
Gross profit.....	<u>872,745</u>	<u>1,059,162</u>
Operating expenses:		
Sales and marketing.....	2,089,104	1,425,493
General and administrative.....	1,817,159	1,603,117
Engineering and regulatory.....	<u>779,038</u>	<u>965,472</u>
Total operating expenses.....	<u>4,685,301</u>	<u>3,994,082</u>
Loss from operations.....	<u>(3,812,556)</u>	<u>(2,934,920)</u>
Other (expense) income:		
Interest expense.....	(241,197)	(207,314)
Interest income.....	47,414	14,722
Loss from early extinguishment of convertible subordinated bridge notes.....	(335,410)	
Other income (expense).....	<u>44,084</u>	<u>(111,317)</u>
Total other expense.....	<u>(485,109)</u>	<u>(303,909)</u>
Net loss.....	<u>\$ (4,297,665)</u>	<u>\$ (3,238,829)</u>
Basic and diluted net loss per share.....	<u>\$ (.62)</u>	<u>\$ (.56)</u>
Shares used in computing basic and diluted net loss per share.....	<u>6,980,820</u>	<u>5,787,642</u>

The accompanying notes are an integral part of these financial statements.

**MedicalCV, Inc.**  
**Consolidated Statements of Changes in Shareholders' Equity**

	<u>Common Stock</u>		<u>Additional</u>	<u>Deferred</u>	<u>(Accumulated</u>	
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Stock-Based</u>	<u>Deficit)</u>	<u>Total</u>
			<u>Capital</u>	<u>Compensation</u>		
Total, April 30, 2000 .....	5,023,834	\$ 50,238	\$ 6,779,082	\$ —	\$ (4,868,892)	\$ 1,960,428
Net loss .....					(3,238,829)	(3,238,829)
Common stock issued .....	1,170,000	11,700	2,913,300			2,925,000
Exercise of stock options .....	255,000	2,550	673,199			675,749
Repurchase of common stock in connection with stock option exercises .....	(120,000)	(1,200)	(298,800)			(300,000)
Deferred stock-based compensation .....			20,075	(20,075)		
Amortization of stock-based compensation ..				3,251		3,251
Issuance of common stock for compensation .....	15,000	150	41,850			42,000
Issuance of warrants for compensation .....			162,000			162,000
Stock options issued to non-employees .....			123,050			123,050
Warrants issued in connection with bank line of credit guarantee .....			76,622			76,622
Total, April 30, 2001 .....	6,343,834	63,438	10,490,378	(16,824)	(8,107,721)	2,429,271
Net loss .....					(4,297,665)	(4,297,665)
Common stock issued, net of issuance costs of \$1,353,515 .....	1,500,000	15,000	5,381,485			5,396,485
Warrants issued in connection with issuance of common stock .....			50			50
Amortization of stock-based compensation ..				7,762		7,762
Stock options issued to non-employees .....			69,844			69,844
Discount on convertible subordinated bridge notes .....			497,125			497,125
Warrants issued in connection with convertible subordinated bridge notes .....			500			500
Repurchase of beneficial conversion feature related to early extinguishment of convertible subordinated bridge notes .....			(77,332)			(77,332)
Total, April 30, 2002 .....	7,843,834	\$ 78,438	\$ 16,362,050	\$ (9,062)	\$ (12,405,386)	\$ 4,026,040

The accompanying notes are an integral part of these financial statements.

**MedicalCV, Inc.**  
**Consolidated Statement of Cash Flows**

	<u>Year ended April 30,</u>	
	<u>2002</u>	<u>2001</u>
Cash flows from operating activities:		
Net loss .....	\$ (4,297,665)	\$ (3,238,829)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on early extinguishment of convertible subordinated bridge notes .....	335,410	
Depreciation .....	290,049	203,133
Amortization .....	222,191	179,428
Amortization of discount on convertible subordinated bridge notes .....	84,383	
Provision for doubtful accounts .....	133,360	167,222
Provision for inventory obsolescence .....	37,584	67,083
Stock-based compensation .....	77,606	664,801
Changes in assets and liabilities:		
Accounts receivable .....	(185,416)	82,484
Inventories .....	(188,084)	(564,359)
Prepaid expenses and other assets .....	48,361	(22,777)
Accounts payable .....	78,180	(61,474)
Accrued expenses .....	177,236	12,590
Net cash used in operating activities .....	<u>(3,186,805)</u>	<u>(2,510,698)</u>
Cash flows from investing activities:		
Purchase of property, plant and equipment .....	(384,024)	(362,344)
Loan to UROPACE .....	(81,000)	(154,000)
Net cash used in investing activities .....	<u>(465,024)</u>	<u>(516,344)</u>
Cash flows from financing activities:		
Borrowings on bank line of credit .....	1,570,000	2,315,000
Principal payments on bank line of credit .....	(475,000)	(2,130,000)
Principal payments on other long-term debt .....	(42,464)	(17,419)
Borrowings on bridge loans, net .....	438,885	
Principal payments on bridge loans .....	(500,000)	
Principal payments under capital lease obligations .....	(66,929)	(87,906)
Issuance of common stock, net of issuance costs .....	5,396,485	2,925,000
Issuance of warrants .....	550	
Exercise of stock options .....		41,249
Net cash provided by financing activities .....	<u>6,321,527</u>	<u>3,045,924</u>
Net increase in cash and cash equivalents .....	2,669,698	18,882
Cash and cash equivalents at beginning of year .....	111,977	93,095
Cash and cash equivalents at end of year .....	<u>\$ 2,781,675</u>	<u>\$ 111,977</u>
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest .....	\$ 241,197	\$ 93,451
Income taxes .....	1,256	750
Non-cash investing and financing activities:		
Capital lease obligations incurred for the purchase of property, plant, and equipment .....	34,796	
Discount on convertible subordinated bridge notes related to warrants and beneficial conversion feature .....	497,125	
Repurchase of beneficial conversion feature related to early extinguishment of convertible subordinated bridge notes .....	77,332	
Land special assessments due in future years, net .....		162,000
Stock option exercises using common stock .....		337,500
Issuance of common stock for compensation .....		42,000
Warrants issued in connection with bank line of credit guarantee .....		76,622

The accompanying notes are an integral part of these financial statements.

**MedicalCV, Inc.**  
**Notes to Consolidated Financial Statements**

**1. Business Description**

MedicalCV, Inc. (the Company) is a corporation engaged in the manufacture and marketing of mechanical monoleaflet heart valves primarily in Europe, South Asia, the Middle East and the Far East.

The Company's consolidated financial statements for the year ended April 30, 2002, have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities and commitments in the normal course of business. The Company has sustained losses and negative cash flows from operations in recent years and expects these conditions to continue for the foreseeable future. At April 30, 2002, the Company had an accumulated deficit of \$12,405,386, and has insufficient funds to meet the requirements of its revolving line of credit, which matures November 2002, and finance its working capital and capital expenditure needs. Accordingly, these matters raise substantial doubt about the Company's ability to continue as a going concern. The Company is currently pursuing the refinancing of its revolving line of credit and seeking other financing to fund its operations and working capital requirements. If the Company is unable to refinance its revolving line of credit and obtain funds by the end of calendar year 2002, it will be required to significantly revise its business plans and drastically reduce operating expenditures such that it may not be able to develop or enhance its products, gain market share in the United States or respond to competitive pressures or unanticipated requirements, which could seriously harm its business, financial position and results of operations.

The Company is subject to risks and uncertainties common to rapidly growing medical technology-based companies, including rapid technological change, dependence on one principal product, new product development and acceptance, actions of competitors, dependence on key personnel and United States market penetration.

**2. Summary of Significant Accounting Policies**

**Principles of Consolidation**

The Company's consolidated financial statements include the accounts of MedicalCV, Inc. and its wholly-owned subsidiaries, CV Holdings, Inc., CVD International, Inc. and its 80 percent-owned dormant subsidiary Medical Europe CVD which was liquidated in fiscal 2001 with no material impact to the financial statements. All significant intercompany transactions and balances have been eliminated in consolidation.

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**Fair Value of Financial Instruments**

The Company's financial instruments consist primarily of cash and cash equivalents, trade accounts receivable and accounts payable for which the current carrying amounts approximate fair value. Additionally, the borrowing rates currently available to the Company approximate current rates for debt agreements with similar terms and average maturities.

**Cash and Cash Equivalents**

Cash and cash equivalents consist of checking accounts and a money market account, all of which are held in two depository institutions. The Company considers all highly-liquid investments with original maturities of three months or less to be cash equivalents. The carrying value of cash equivalents approximates fair value because of the short maturity of these instruments. The majority of the Company's cash and cash equivalents are held in two financial institutions. Deposits in these institutions may exceed the amount of federal insurance provided on such deposits.

**Inventories**

Inventories consist of various mechanical heart valves and other medical items that are stated at the lower of cost or market, with cost determined utilizing standard costs, which approximate the first-in, first-out method of inventory valuation.

## **Property, Plant and Equipment**

Property, plant and equipment is stated at cost. Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the related assets. The building is depreciated over a 30-year life. Machinery and equipment, furniture and fixtures, and tooling and software are depreciated over five-year lives. Maintenance and repairs are charged to current operations when incurred. The cost and related accumulated depreciation or amortization of assets disposed of are removed from the related accounts and any resulting gains or losses are recorded to the statement of operations.

## **Long-Lived Assets**

The Company periodically evaluates the carrying value of long-lived assets to be held and used, including but not limited to, capital assets and intangible assets, when events and circumstances warrant such a review. The carrying value of a long-lived asset is considered impaired when the anticipated undiscounted cash flow from such asset is separately identifiable and is less than its carrying value. In that event, a loss is recognized based on the amount by which the carrying value exceeds the fair value of the long-lived asset. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. Losses on long-lived assets to be disposed of are determined in a similar manner, except that fair values are reduced for the cost to dispose. No losses from impairment have been recognized in the financial statements.

## **Revenue Recognition**

The Company recognizes revenues from the sale of its mechanical heart valves provided that the Company has received a purchase order, the price is fixed, title has transferred, collection of the resulting receivable is probable, and there are no remaining obligations. Transfer of title occurs for substantially all sales upon shipment. The Company's products are not subject to any customer acceptance process. There are no rights of return unless the product does not perform according to specifications.

## **Research and Development**

Research and development costs are expensed as incurred.

## **Stock-Based Compensation**

The Company accounts for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and complies with the disclosure provisions of Statement of Financial Accounting Standard (SFAS) No. 123, "Accounting for Stock-Based Compensation." The Company accounts for stock-based compensation to non-employees using the fair value method prescribed by Emerging Issues Tax Force (EITF) Issue 96-18.

## **Income Taxes**

Deferred income taxes are recorded to reflect the tax consequences on future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax asset will not be realized. Income tax expense or benefit is the tax payable or refundable for the year and the change during the year in deferred tax assets and liabilities.

## **Comprehensive Income (Loss)**

Comprehensive income (loss) includes net income (loss) and items defined as other comprehensive income (loss). Items defined as other comprehensive income (loss) include items such as foreign currency translation adjustments and unrealized gains and losses on certain marketable securities. For the years ended April 30, 2002 and 2001, there were no adjustments to net loss to arrive at comprehensive loss.

## **Concentration of Credit Risk**

At April 30, 2002 and 2001, approximately 68 percent and 59 percent, respectively, of the Company's accounts receivable were due from several distributors that individually accounted for 10 percent or more of the Company's net sales in

each respective fiscal year (see Note 10). The Company generally requires no collateral from its customers with respect to trade accounts receivable. The Company maintains an allowance for doubtful accounts based upon its historical experience and the expected collectibility of all accounts receivable.

### **Net Income (Loss) Per Share**

Net income (loss) per share is computed under the provisions of SFAS No. 128, "Earnings Per Share." Basic net income (loss) per common share is computed using net income (loss) and the weighted-average number of shares of common stock outstanding. Diluted earnings per share reflect the potential dilution of securities that could share in the earnings of an entity. Diluted net loss per common share does not differ from basic net loss per common share in the years ended April 30, 2002 and 2001 since 3,551,390 and 815,140, respectively, of potential dilutive shares of common stock from exercise of stock options and warrants are anti-dilutive.

### **Reclassifications**

Certain amounts previously reported have been reclassified to conform to their fiscal year 2002 presentation. These reclassifications had no effect on net loss, cash flows or shareholders' equity as previously reported.

### **New Accounting Pronouncements**

In June 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, "Business Combinations," which addresses accounting and financial reporting for business combinations. Also in June 2001, the FASB issued SFAS No. 142, "Goodwill and Other Intangible Assets," which addresses how intangible assets acquired individually or with a group of other assets, except for those acquired in a business combination, should be accounted for in financial statements upon their acquisition and also addresses how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. Both of these statements are effective in their entirety for the Company on May 1, 2002. The adoption of these statements will not have a material impact on the current financial position or results of operations of the Company.

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Disposal of Long-Lived Assets," which addresses accounting and financial reporting for long-lived assets. This statement is effective for the Company on May 1, 2002. The adoption of this statement is not expected to have a material impact on the current financial position or results of operations of the Company.

In May 2002, the FASB issued SFAS No. 145, "Rescission of SFAS Nos. 4, 44, and 64, Amendments to SFAS No. 13, and Technical Corrections as of April 2002." The new statement amends existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. SFAS No. 145 was adopted by the Company effective May 1, 2001. The adoption of SFAS No. 145 required the classification of the loss on early extinguishment of convertible subordinated bridge notes as a component of net loss from recurring operations for the year ended April 30, 2002 versus being classified as an extraordinary item.

### 3. Supplemental Financial Statement Information

Certain balance sheet components consist of the following at April 30:

<u>Trade Accounts Receivable, Net</u>	<u>2002</u>	<u>2001</u>
Related parties .....	\$ 849,696	\$ 660,557
Other .....	607,577	620,295
Allowance for doubtful accounts .....	(198,657)	(155,292)
	<u>\$ 1,258,616</u>	<u>\$ 1,125,560</u>
<u>Inventories</u>	<u>2002</u>	<u>2001</u>
Raw materials .....	\$ 436,855	\$ 664,990
Work-in-process .....	551,561	423,570
Finished goods .....	1,334,119	1,083,475
	<u>\$ 2,322,535</u>	<u>\$ 2,172,035</u>
<u>Property, Plant and Equipment, Net</u>	<u>2002</u>	<u>2001</u>
Land .....	\$ 182,000	\$ 182,000
Building .....	1,225,190	1,166,085
Machinery and equipment .....	1,512,611	1,233,933
Furniture and fixtures .....	177,513	139,481
Tooling .....	100,263	84,163
Software .....	112,271	85,366
	3,309,848	2,891,028
Accumulated depreciation and amortization .....	(1,734,695)	(1,444,646)
	<u>\$ 1,575,153</u>	<u>\$ 1,446,382</u>
<u>Deferred Financing Costs</u>	<u>2002</u>	<u>2001</u>
Deferred financing costs .....	\$ 345,351	\$ 345,351
Accumulated amortization .....	(272,491)	(111,415)
	<u>\$ 72,860</u>	<u>\$ 233,936</u>

#### 4. Long-Term Debt and Convertible Subordinated Bridge Notes

Long-term debts consist of the following at April 30:

	<u>2002</u>	<u>2001</u>
Revolving credit line with Associated Bank, interest is payable monthly and the principal is due November 2002, collateralized by the Company's real estate and other business assets excluding accounts receivable .....	\$ 2,500,000	\$ 1,405,000
Promissory note with Dakota Electric Association, principal and interest due in monthly installments through May 2009, interest at 5.75%, collateralized by the Company's lighting equipment and rooftop air-conditioning units .....	165,983	184,447
Land special assessments payable to Dakota County, principal and interest due in semi-annual installments through May 2010, interest at 8%.....	<u>216,000</u>	<u>240,000</u>
	2,881,983	1,829,447
Less current maturities.....	<u>(2,542,460)</u>	<u>(42,460)</u>
	<u>\$ 339,523</u>	<u>\$ 1,786,987</u>

Scheduled maturities of long-term debt are as follows:

<u>Year Ending April 30,</u>	<u>Amount</u>
2003.....	\$ 2,542,460
2004.....	44,704
2005.....	45,926
2006.....	47,221
2007.....	48,592
Thereafter .....	<u>153,080</u>
	<u>\$ 2,881,983</u>

On November 23, 1999, the Company obtained a \$2,500,000 revolving credit line with Associated Bank. The line of credit is due November 23, 2002 in one payment of all outstanding principal plus all accrued unpaid interest, and is collateralized by the Company's real estate and other business assets, excluding accounts receivable. In addition, a shareholder and a member of the Board of Directors of the Company has provided a \$2,000,000 personal guarantee and has pledged marketable securities with a guaranteed value of \$1,100,000 to support repayment of borrowings on the credit line. Interest is required to be paid monthly and accrues at the Wall Street Journal Prime Rate. The interest rate at April 30, 2002 and 2001 was 4.75 percent and 7.5 percent, respectively. As part of the credit agreement, the Company was formerly required to maintain a minimum tangible net worth of not less than \$3,000,000 on a quarterly basis. At April 30, 2001, the Company failed to comply with the minimum tangible net worth covenant; on August 24, 2001, the Company received an amendment retroactively changing the minimum tangible net worth to not less than \$1,000,000 on a monthly basis. The Company was in compliance with its debt covenants as of April 30, 2002.

#### Convertible Subordinated Bridge Notes

On August 21, 2001, the Company sold units of convertible subordinated bridge notes with an aggregate principal amount of \$500,000 and redeemable warrants to purchase an aggregate of 500,000 shares of the Company's common stock for total proceeds of \$500,500. Each unit consisted of a \$25,000 principal amount 10 percent convertible subordinated bridge note and redeemable warrants to purchase 25,000 shares of the Company's common stock at a price of \$6.50 per share. The notes are unsecured and were due in August 2002. The Company had the option to prepay the notes without premium or penalty. If the fair value of the Company's common stock or units equalled or exceeded \$8.50 per share, for ten consecutive trading days, the Company could, at its option, require conversion of the notes into its common stock at a price of \$6.50 per share and redeem the outstanding warrants for \$0.01 each. The warrants are immediately exercisable and have a term of five years.



The allocated fair value of the warrants of \$308,236 and the value of the beneficial conversion feature of \$188,889 as of August 21, 2001 are accounted for as a discount on the convertible subordinated bridge notes. This discount, which is presented as a reduction of the face value of the Notes on the consolidated balance sheet, was amortized as part of interest expense over the one-year life of the Notes using the effective interest method.

During the fourth quarter of 2002, the Company early extinguished the convertible subordinated bridge notes. On the date of extinguishment, \$77,332 of the remaining discount, representing the repurchase of the beneficial conversion feature, was treated as a reduction of Additional Paid-in Capital with the balance of the discount of \$335,410 being charged to other expense.

## 5. Leases

### Operating Leases

The Company leases certain manufacturing equipment under various operating lease agreements which expire at various dates through fiscal year 2003. At the end of the lease terms, the Company has the option to renew the leases, purchase the equipment at fair value, or return the equipment. Minimum payments under operating leases with non-cancelable terms total \$19,742 for fiscal year 2003.

Rental expense under operating leases was \$66,874 and \$107,870 in fiscal years 2002 and 2001, respectively.

### Capital Leases

The Company leases certain manufacturing equipment under various capital leases. The equipment is leased under agreements expiring through fiscal year 2004 with implicit interest rates ranging from 6.9 percent to 16.2 percent. The Company may elect to purchase the equipment under bargain purchase options at the end of the lease terms. The leases are collateralized by the underlying equipment with a total cost of \$322,733 and accumulated amortization of \$225,958 and \$168,371 at April 30, 2002 and 2001, respectively.

Scheduled lease payments under capital lease obligations are as follows:

<u>Fiscal Year</u>	
2003.....	\$ 67,480
2004.....	45,456
Total minimum lease payments.....	<u>112,936</u>
Less interest .....	11,013
Present value of capital lease obligations.....	<u>101,923</u>
Less current portion .....	(59,854)
Capital lease obligations, less current portion .....	<u>\$ 42,069</u>

## 6. Income Taxes

The components of deferred income tax assets at April 30 are as follows:

	2002	2001
Federal net operating loss carryforwards .....	\$ 3,863,200	\$ 2,508,200
Research and experimentation credit carryforwards .....	524,200	469,000
State net operating loss carryforwards .....	245,800	169,500
Other carryforwards .....	78,800	79,300
Inventories .....	86,000	73,700
Allowance for uncollectible accounts .....	147,400	52,800
Property, plant and equipment .....	44,900	54,100
Accrued expenses and other .....	37,400	24,300
Total deferred tax assets .....	5,027,700	3,430,900
Valuation allowance .....	(5,027,700)	(3,430,900)
Net deferred tax asset .....	\$ —	\$ —

The Company has established valuation allowances to fully offset tax assets due to the inherent uncertainty of predicting the sufficiency of future taxable income necessary to realize these deferred tax assets, particularly in light of the Company's recent history of significant operating losses. In addition, future utilization of available net operating loss carryforwards may be limited under Internal Revenue Code 382 as a result of future changes in ownership.

The Company's federal net operating loss carryforwards of approximately \$11,362,327 and state net operating loss carryforwards of \$3,570,754 expire in fiscal years 2013 through 2022. Available research and experimentation credits at April 30, 2002 represent federal and state amounts of \$354,603 and \$111,930, respectively, with expiration dates in fiscal years 2010 through 2021.

The reconciliation of the U.S. statutory federal income tax rate with the effective rate for the years ended April 30, 2002 and 2001, is as follows:

	2002	2001
Tax benefit at statutory rate .....	\$ (1,355,000)	\$ (638,000)
Research and experimentation tax credits .....	(55,200)	(172,300)
State taxes, net of federal benefit .....	(76,300)	(19,600)
Nondeductible expenses .....	(97,700)	(91,700)
Other .....	(12,600)	(166,900)
Change in valuation allowance .....	1,596,800	1,088,500
Total income tax (benefit) provision .....	\$ —	\$ —

## 7. Shareholders' Equity

### Common Stock

On January 25, 2001, the Company gave a stock bonus of 15,000 shares of the Company's common stock to an officer of the Company. The estimated fair value of the shares of \$42,000 was recorded as a general and administrative expense.

On November 27, 2001, the Company closed on its initial public offering (IPO). In connection with the IPO, the Company issued 1,500,000 units at a price of \$4.50 per unit for gross proceeds of \$6,750,000. After offering costs, the Company received net proceeds of \$5,396,485. Each unit consisted of one share of common stock and one redeemable Class A Warrant. Each Class A Warrant becomes exercisable, and may be transferred separately from the common stock, on or after May 20, 2003. When each Class A Warrant becomes exercisable, the holder will be entitled to purchase, at any time until November 20, 2004, one share of common stock at an exercise price of \$6.50 per share, subject to customary anti-dilution

adjustments. The Company may redeem the Class A Warrants for \$0.01 per warrant at any time once they become exercisable, upon ten business days' written notice, if the closing price of the Company's common stock or units exceeds \$8.50, subject to customary anti-dilution adjustments, for any ten consecutive trading days before such notice.

## Stock Options

The Company has authorized the issuance of stock options for the aggregate purchase of 2,653,034 shares of common stock under various plans covering certain employees, members of the Board of Directors and certain independent contractors approved by the Board of Directors. Options are typically granted at prices not less than fair market value at the date of grant. Options generally become exercisable between one to three years after grant date and have a maximum term of three to ten years depending on the plan.

The following is a summary of stock option activity with respect to the Company's various plans and includes option activity for employees, directors and non-employees:

	Options	Weighted Average Exercise Price Per Share
Outstanding, April 30, 2000 .....	801,680	\$ 2.50
Granted.....	422,640	2.50
Expired.....	(514,180)	2.60
Exercised.....	(255,000)	1.34
Outstanding, April 30, 2001 .....	455,140	\$ 3.03
Granted.....	591,250	3.79
Expired.....	(5,000)	5.00
Outstanding, April 30, 2002 .....	1,041,390	\$ 3.46

At April 30, 2002 and 2001, 655,534 and 498,608 options, respectively, were available for grant under the Company's stock option plans. On August 9, 2001, the Company's shareholders approved the 2001 Equity Incentive Plan (2001 Plan) and reserved 500,000 shares of common stock for issuance upon exercise of stock options to be granted under the 2001 Plan to employees, officers, consultants, advisors, employee and non-employee directors and employees of certain related entities. The number of shares reserved for issuance under the 2001 Plan increases on January 1 of each year by the greater of 50,000 shares or 3.5 percent of the outstanding shares of the Company's common stock on such date, unless the Board of Directors sets the increase at a lower number of shares. On January 1, 2002, the number of shares reserved under the 2001 Plan increased by 274,534 shares pursuant to the foregoing provision.

The following table summarizes information about stock options outstanding and exercisable at April 30, 2002:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$2.36 – \$5.00	1,041,390	4.66	\$ 3.46	610,040	\$ 3.92

During the years ended April 30, 2002 and 2001, the Company issued fully vested, four and five-year options to purchase an aggregate of 37,500 and 85,000 shares of the Company's common stock at exercise prices of \$2.53 to \$4.50 and \$2.50 per share, respectively, to certain non-employees who provided technical advisory services to the Company. The aggregate fair value of the options using the Black-Scholes valuation model was \$69,844 and \$123,050 and were fully expensed in fiscal years 2002 and 2001. The following assumptions were used to value the options for the years ended April 30, 2002 and 2001:

	2002	2001
Dividend yield rate .....	0 percent	0 percent
Risk free interest rate .....	3.91 percent	5.69 percent
Expected life .....	4 to 10 years	4 to 6 years
Volatility .....	85 percent	69 percent

Deferred compensation relating to stock options granted below fair value during the year ended April 30, 2001 was \$20,075. Such deferred compensation will be amortized over the vesting periods of the related stock options, which generally range from three to five years. This compensation is recognized on an accelerated basis in accordance with FASB Interpretation (FIN) No. 28. Compensation expense relating to stock options granted below fair market value of \$7,762 and \$3,251 was recognized during the years ended April 30, 2002 and 2001.

During the year ended April 30, 2001, certain employees exercised stock options by surrendering an aggregate of 120,000 shares of the Company's common stock as consideration for the exercise price. In connection with this form of exercise, the Company recorded compensation expense of \$334,500 with the offsetting amount increasing additional paid-in capital.

If the Company had elected to recognize compensation expense for options granted based on the minimum value of the options granted at the date of grant as prescribed by SFAS No. 123, the Company's net loss for fiscal years 2002 and 2001 would have been as follows:

	2002	2001
As reported.....	\$ (4,297,665)	\$ (3,238,829)
Pro forma.....	(5,249,444)	(3,470,775)
Net loss per common share - basic and diluted:		
As reported.....	(.62)	(.56)
Pro forma .....	(.75)	(.60)

During the year ended April 30, 2002, for purposes of determining fair value using the Black-Scholes option pricing model as prescribed by SFAS No. 123, the Company used the contractual life of the options as the expected holding period for employees and the life of the options for directors. The risk-free interest rate for 2002 was 4.71 percent, the dividend yield used was 0 percent and the volatility factor was 85 percent.

During the year ended April 30, 2001, for purposes of determining minimum value using the Black-Scholes option pricing model as prescribed by SFAS No. 123, the Company used 95 percent of the life of the options as the expected holding period for employees and the life of the options for directors. The risk-free interest rate for 2001 was 5.75 percent. The dividend yield used was 0 percent and volatility factors were not applicable.

### Stock Warrants

At April 30, 2002 and 2001, the Company had outstanding and exercisable warrants to purchase 2,510,000 and 360,000 shares, respectively, of the Company's common stock at prices ranging from \$2.00 to \$6.75 per share. The warrants expire at various dates through February 1, 2006. At April 30, 2002 and 2001, the weighted average remaining contractual life of the warrants was 3.14 and 4.23 years and the weighted average exercise price of the warrants was \$5.91 and \$2.25, respectively.

On February 1, 2001, the Company issued a fully-vested, four-year warrant to purchase 240,000 shares of the Company's common stock at \$2.125 per share to an officer of the Company in connection with a separation agreement. The intrinsic value of the warrant was \$162,000 and was fully expensed in fiscal year 2001.

In November 1999 and December 2000, the Company issued fully vested four-year warrants to purchase an aggregate of 100,000 shares of common stock exercisable at \$2.00 per share to a board member in connection with a bank line of credit guarantee. The fair value of the warrants was calculated using the Black-Scholes valuation model and \$76,622 was capitalized as deferred financing costs in fiscal year 2001. The deferred financing costs are being amortized to interest expense on a straight-line basis over the life of the guarantee. The following assumptions were used to value the warrants: dividend yield of

0 percent, risk-free interest rate of 5.69 percent, expected life equal to the contractual life of four years and volatility of 69 percent. At April 30, 2002, the unamortized balance was \$19,155.

## 8. Research and Development Costs

Research and Development costs principally consist of engineering costs, included as part of engineering and regulatory in the Consolidated Statement of Operations, totaled \$496,685 and \$800,625 for the fiscal years ended April 30, 2002 and 2001, respectively. Research and Development costs relate primarily to product and process development initiatives.

## 9. Supply Agreement

In July 1998, the Company entered into a three-year supply agreement with Sulzer Carbomedics, Inc. (Carbomedics), the source of certain raw material components associated with the manufacture of certain of the Company's heart valves. The supply agreement was extended for an additional two years in March 2001.

This agreement provides that the Company purchase a minimum number of raw material units each calendar year through 2003. Under the terms of the agreement, the Company is required to compensate Carbomedics for any purchase shortfalls up to a maximum of \$200,000 per year. The Company has not met the minimum purchase requirement for the last three calendar years and does not believe it will meet the minimum purchase requirement for calendar year 2002. As a result, the Company expensed \$148,991 and \$108,174 related to these purchase shortfalls to cost of goods sold in fiscal years 2002 and 2001, respectively.

## 10. Segment and Related Party Information

The Company views its operations and manages its business as one segment, the manufacturing and marketing of mechanical monoleaflet heart valves. Factors used to identify the Company's single operating segment include the organizational structure of the Company and the financial information available for evaluation by the chief operating decision maker. The following table summarizes net sales by geographic area:

	For the Years Ended	
	April 30,	
	2002	2001
Europe.....	\$ 1,938,847	\$ 1,636,825
South Asia.....	488,940	634,030
Middle East .....	209,346	234,726
Far East.....	306,735	256,924
Other.....	38,330	100,935
Total.....	<u>\$ 2,982,198</u>	<u>\$ 2,863,440</u>

At April 30, 2002 and 2001, substantially all of the Company's operations and assets are based in the United States.

The Company distributes its products primarily through distributor organizations that, in turn, market the product directly to medical institutions. Three of these distributors are shareholders of the Company with ownership interests of up to approximately 6 percent each. An affiliate of one of these shareholder distributors is also a member of the Company's Board of Directors. Sales to distributors that individually account for 10 percent or more of the Company's net sales in each respective fiscal year are as follows (related party distributors are separately presented below regardless of sales level):

	2002	2001
Distributor #1 (related party) .....	\$ 1,421,960	\$ 1,170,700
Distributor #2 (related party) .....	15,300	130,980
Distributor #3.....	443,940	424,520
Distributor #4 (related party) .....	13,300	

Aggregate accounts receivable from the above three related party distributors at April 30, 2002 and 2001 totaled \$849,696 and \$660,557, respectively.

## **11. Spin-off of UROPACE**

On November 1, 2000, the Company completed the spin-off of UROPACE, Inc. (UROPACE), a subsidiary of the Company, to the existing shareholders of the Company. The separation was effected by transferring from the Company to UROPACE all assets, tangible and intangible, relating to the development of female urinary incontinence technology. Shareholders of record on September 15, 2000 received one share of common stock of UROPACE for each 6.882 shares of the Company's common stock held on that date.

The assets transferred to UROPACE had no book value at November 1, 2000 and the operations of UROPACE prior to the spin-off had no revenues and minimal expenses during the fiscal year ended April 30, 2001. As a part of this spin-off, the Company agreed to loan UROPACE up to \$356,250 at a variable interest rate. Principal and interest on the note will be payable in installments equal to 5 percent of UROPACE's future annual net sales until the note and interest is paid in full. The Company had loaned UROPACE \$235,000 and \$154,000 at April 30, 2002 and 2001. Due to the development stage of UROPACE and the uncertainty associated with the collection of this amount, the Company has recorded an allowance for the entire balance of the loan at April 30, 2001, with the corresponding expense included in other income (expense) in the Consolidated Statement of Operations.

## **12. Savings and Retirement Plan**

The Company sponsors a 401(k) savings and retirement plan (the Plan) which is available to all eligible employees. Under the Plan, the Company may make a discretionary contribution to the Plan upon approval by the Company's Board of Directors. Employees are fully vested in their own contributions and earnings thereon and become fully vested in the Company's contributions and earnings thereon after three years of service. The Company made contributions to the Plan of \$16,475 and \$14,764 in fiscal years 2002 and 2001, respectively.

## **ITEM 8 CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

The disclosure called for by paragraph (a) of this item has been "previously reported" as that term is defined in Rule 12b-2 under the Exchange Act.

### PART III

#### ITEM 9 DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

The following table provides information with respect to our directors and executive officers as of April 30, 2002. Our executive officers serve at the discretion of our board of directors. Our directors hold office until our next annual meeting of shareholders and until their successors have been elected and qualified. There are no family relationships among our directors and executive officers.

<u>Name</u>	<u>Age</u>	<u>Principal Occupation</u>	<u>Position with MedicalCV</u>	<u>Director Since</u>
Adel A. Mikhail, Ph.D.	67	Chairman of the Board of MedicalCV	Chairman of the Board	1992
Blair P. Mowery	56	President, Chief Executive Officer and Director of MedicalCV	President, Chief Executive Officer and Director	2001
Jules L. Fisher	48	Chief Financial Officer of MedicalCV	Chief Financial Officer	N/A
Allan R. Seck	56	Senior Vice President -Sales and Marketing of MedicalCV	Senior Vice President — Sales and Marketing	N/A
Ronald M. Bosrock	63	Founder and Executive Director of the Global Institute	Director	1999
Salvador Mercé Cervelló	46	Managing and General Director of Mercé V. Electromedicina, S.L.	Director	1996
Norman Dann	75	Consultant to the Medical Device Industry	Director	1995
Richard A. DeWall, M.D.	75	Retired Cardiovascular Surgeon	Director	1992
Paul K. Miller	79	President of Acton Construction Management Company	Director	1994

*Adel A. Mikhail, Ph.D.* became Chairman of the Board, President and Chief Executive Officer in March 1992. While he continues to serve our company as Chairman of the Board and as a consultant, he retired as Chief Executive Officer and President in June 2001. Dr. Mikhail has more than 29 years of experience in the mechanical heart valve industry, including 17 years with our predecessors, Medical Incorporated and Omnicor. Dr. Mikhail served such entities in several technical capacities, including Senior Vice President of Clinical Research and Regulatory Affairs. In that capacity, Dr. Mikhail led the team that successfully obtained FDA marketing clearance of the Omniscience heart valve. Dr. Mikhail is named as an inventor in patents in the urology and heart valve fields.

*Blair P. Mowery* became our President and Chief Executive Officer in June 2001 and was appointed to our board of directors in July 2001. After serving our company as an independent advisor through his wholly-owned company, Bioscrene Ltd., from February 1996 to August 1996, he joined us in August 1996 as Vice President - Business Development and was promoted to Chief Operating Officer in 1999. From April 1991 through December 1993, Mr. Mowery was President and Chief Operating Officer of GalaGen, Inc., a biopharmaceutical company. From March 1987 to March 1991, he was President of Procor Technologies, a joint venture with Abbott Ross Laboratories and the predecessor company to GalaGen.

*Jules L. Fisher* became our Chief Financial Officer in January 2002. From October 1996 to December 2001, Mr. Fisher served as Vice President and Chief Financial Officer of Minntech Corporation, a manufacturer of medical supplies and devices, sterilants, and filtration and separation products primarily for kidney dialysis, open-heart surgery and endoscopy. From August 1991 to October 1996, he held the position of Director, Operations Accounting for U.S. Surgical Corp. Mr. Fisher also served as Director, Financial Reporting and Analysis in the Pharmaceutical Group of Bristol-Myers Squibb Company from May 1987 to February 1991.

*Allan R. Seck* joined our company in May 1999 as Vice President - Sales and Marketing. In March 2001, he was promoted to Senior Vice President - Sales and Marketing. From May 1996 until May 1999, Mr. Seck served as Vice President

- Sales and Marketing for AVECOR Cardiovascular, Inc., where he was responsible for sales, marketing, customer service, technical support, customer education and shipping. He has also held senior management positions with Biomedicus, Inc., the cardiopulmonary division of Medtronic, and Johnson & Johnson Cardiovascular.

*Ronald M. Bosrock*, one of our directors since July 1999, is the founder and executive director of the Global Institute. He currently holds a John Myers Chair of Management at St. John's University in Minnesota. Mr. Bosrock has 30 years of experience in the banking and manufacturing industries and has served as managing director of Arthur Andersen International.

*Salvador Mercé Cervelló*, one of our directors, serves as Managing and General Director of Mercé V. Electromedicina, S.L., a commercial supplier of electromedical products, mainly products for cardiac surgery and cardiology, including those produced by our company, in Spain. He served on our board from November 1993 to November 1995 and again from December 1996 through the present.

*Norman Dann* has been a director of our company since September 1995. Between 1980 and 1992, Mr. Dann was a general partner in and co-founder of Pathfinder Ventures, Inc., a venture capital business. Since 1992, he has been a consultant to the medical device industry. Mr. Dann is a member of the board of directors of Medwave, Inc.

*Richard A. DeWall, M.D.*, a retired cardiovascular surgeon, has been one of our directors since November 1992. Dr. DeWall has over 35 years of experience in heart valve replacement and was instrumental in implanting the first Omniscience heart valve. He was a medical professor at the Chicago Medical School and is credited with developing the first workable heart-lung machine for use during open heart surgery.

*Paul K. Miller*, one of our directors since August 1994, has served as President of Acton Construction Management Company, a real estate management company, since 1980.

#### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our officers, directors and persons who own more than 10% of a registered class of our equity securities to file reports of ownership and changes in ownership with the SEC. Such officers, directors and shareholders are required by the SEC to furnish us with copies of all such reports. To our knowledge, based solely on a review of copies of reports filed with the SEC during the last fiscal year, all applicable Section 16(a) filing requirements were met, except that one report on Form 3 for each of our then executive officers and directors was not filed by November 20, 2001, the effective date of the registration statement covering our initial public offering. The reports on Form 3 for Adel A. Mikhail, Ph.D., Blair P. Mowery, George M. Wettstaedt, Allan R. Seck, Ronald M. Bosrock, Salvador Mercé Cervelló, Norman Dann, Richard A. DeWall, M.D. and Paul K. Miller were filed on November 29, 2001.



## ITEM 10 EXECUTIVE COMPENSATION

The following table sets forth information with respect to compensation paid by us to our Chief Executive Officer and the other highest paid executive officers (the "Named Executive Officers") during our most recent fiscal years.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Annual Compensation			Long-Term Compensation	
		Salary (\$)	Bonus (\$)	Other Annual Compensation (\$)	Awards  Securities Underlying Options	Payouts  All Other Compensation (\$)
Adel A. Mikhail, Ph.D. (1) Chairman of the Board	2002	0	0	0	7,000(2)	59,422(3)
	2001	143,960	0	0	240,000(4)	120,833(5)
Blair P. Mowery (6) President and Chief Executive Officer	2002	170,298	50,000	0	300,000	0
	2001	131,489	0	42,000(7)	0	0
Allan R. Seck Senior Vice President - Sales and Marketing	2002	139,775	0	0	0	0
	2001	131,002	0	0	0	100,000

- (1) Dr. Mikhail served as our President and Chief Executive Officer until June 15, 2001.  
(2) Represents an option grant issued to Dr. Mikhail for serving as a Director on the Company's Board.  
(3) Represents severance compensation paid under our separation agreement with Dr. Mikhail.  
(4) Represents a warrant issued on February 1, 2001 under our separation agreement with Dr. Mikhail.  
(5) Represents severance compensation paid under our separation agreement with Dr. Mikhail.  
(6) Mr. Mowery, who previously served as our Chief Operating Officer, became our President and Chief Executive Officer on June 15, 2001.  
(7) Represents the market value of 15,000 shares of common stock awarded to Mr. Mowery on January 25, 2001.

### OPTION GRANTS IN LAST FISCAL YEAR

The following table sets forth information concerning grants of stock options during the fiscal year ended April 30, 2002 to each executive officer named in the Summary Compensation Table. We granted no stock appreciation rights during our last fiscal year.

Name	Individual Grants			
	Number of Securities Underlying Options Granted	Percent of Total Options Granted to Employees in Fiscal Year	Exercise Price (\$/share)	Expiration Date
Adel A. Mikhail, Ph.D.	7,000	1.3%	\$ 4.50	08-15-06
Blair P. Mowery	300,000	57.1%	\$ 4.50	06-15-06
Allan R. Seck	0	0%	N/A	N/A

The following table sets forth information concerning the options exercised by each executive officer named in the Summary Compensation Table during the fiscal year ended April 30, 2002. It also sets forth information concerning unexercised options held by such persons as of April 30, 2002. No stock appreciation rights were exercised by such persons during the last fiscal year or were outstanding at the end of that year.

# **AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR END OPTION VALUES**

Name	Shares Acquired on Exercise	Value Realized (\$)	Number of Securities Underlying Unexercised Options at Fiscal Year End		Value of Unexercised In the Money Options at Fiscal Year End (\$) (1)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Adel A. Mikhail, Ph.D	0	N/A	0	7,000	N/A	0
Blair P. Mowery	0	N/A	300,000	0	0	N/A
Allan R. Seck	0	N/A	40,000	60,000	0	0

(1) Represents the fair market value of one share of our common stock at April 30, 2002 minus the exercise price.

## **Employment Agreements**

We entered into a separation agreement and release effective as of November 1, 2000 with Adel A. Mikhail, Ph.D., our former President and Chief Executive Officer. Under this agreement, we have made severance and consulting payments to Dr. Mikhail. For information regarding these compensatory arrangements, please refer to Certain Relationships and Related Transactions.

Under an employment agreement effective June 15, 2001, we employ Blair P. Mowery as our President and Chief Executive Officer at a salary of \$165,000 per year. This agreement has a term of two years. It prohibits Mr. Mowery from competing with our company during its term and for 12 months thereafter. This agreement also provides that if either we terminate Mr. Mowery's employment without cause or Mr. Mowery resigns with six months' notice, we will make severance payments to him equal to his monthly base salary for 18 months. In consideration of Mr. Mowery's entry into this agreement, on June 15, 2001, we granted him a stock option to purchase 300,000 shares of our common stock at a price of \$4.50 per share. Such option is immediately exercisable. In addition, we have agreed to pay Mr. Mowery a bonus of \$50,000 for services in fiscal year 2002 subject to achievement of goals agreed upon by Mr. Mowery and our board of directors.

In May 1999, we entered into a letter agreement with Allan R. Seck. Under this agreement, Mr. Seck was employed to serve as our Vice President - Sales and Marketing at a salary of \$132,000 per year plus a bonus of one percent of sales over \$3,500,000 per year. We have the right to terminate Mr. Seck's employment at will. However, upon a change in control of our company, we have agreed to pay him an amount equal to two years' salary and accelerate the vesting of Mr. Seck's unvested stock options to be immediately exercisable. In consideration of Mr. Seck's entry into this agreement, we granted him a stock options to purchase 100,000 shares of our common stock at a price of \$2.50 per share. Such options vest over four years and expire on July 26, 2005. In August 2001, we amended this agreement to provide that the bonus based on annual sales would be payable through fiscal year 2002. In consideration of Mr. Seck's entry into this amendment, we agreed to increase his salary by an amount not to exceed 15% and develop a new executive and sales incentive plan in which he will participate.

## **Director Compensation**

Our directors are reimbursed for certain reasonable expenses incurred in attending board meetings. Directors who are also employees receive no remuneration for services as members of the board or any board committee. Under our director stock option plan, directors who are not employed by us are entitled to receive annual grants of stock options.

## **ITEM 11 SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS**

The following table sets forth certain information known to us regarding beneficial ownership of our common stock as of April 30, 2002, by: (a) each person who is known to us to own beneficially more than five percent of our common stock, (b) each director, (c) each Named Executive Officer (as defined herein), and (d) all executive officers and directors as a group. The percentage of beneficial ownership is based on 7,843,834 shares outstanding as of April 30, 2002. As indicated in the footnotes, shares issuable pursuant to warrants and options are deemed outstanding for computing the percentage of the person holding such warrants or options but are not deemed outstanding for computing the percentage of any other person. Unless otherwise noted, each person identified below has sole voting and investment power with respect to such shares. Except as otherwise noted below, we know of no agreements among our shareholders which relate to voting or investment power with

respect to our common stock. Unless otherwise indicated, the address for each listed shareholder is c/o MedicalCV, Inc., 9725 South Robert Trail, Inver Grove Heights, Minnesota 55077.

<u>Name and Address of Beneficial Owner (1)</u>	<u>Number of Shares Beneficially Owned (1)</u>	<u>Percent Beneficially Owned (1)</u>
Paul K. Miller.....	1,715,580(2)	21.5%
Adel A. Mikhail, Ph.D. ....	739,552(3)	9.1
Graphite Enterprise Trust PLC .....	630,000(4)	8.0
4 <sup>th</sup> Floor, Berkeley Square House Berkeley Square, London W1X 5PA United Kingdom		
Salvador Mercé Vives.....	519,232(5)	6.6
Plaza America, 5 Valencia, Spain		
Hilmar Siebecker .....	405,000	5.2
Staffelstrasse 8 D-67292 Kirchheimbolanden, Germany		
N.G.C. Medical S.p.A.....	400,000	5.1
Via Novedratese 35 22060 Novedrate, Como, Italy		
Richard A. DeWall, M.D. ....	324,780(6)	4.1
Blair P. Mowery.....	315,000(7)	3.9
Salvador Mercé Cervelló .....	133,000(8)	1.7
Allan R. Seck .....	50,000(9)	*
Norman Dann.....	48,000(10)	*
Ronald M. Bosrock.....	24,000(11)	*
Jules L. Fisher .....	0	0
All directors and executive officers as a group (9 persons).....	3,349,912(12)	38.6%

\* Less than one percent.

- (1) Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to securities. Securities "beneficially owned" by a person may include securities owned by or for, among others, the spouse, children or certain other relatives of such person as well as other securities as to which the person has or shares voting or investment power or has the option or right to acquire within 60 days of April 30, 2002.
- (2) Includes 120,000 shares owned by Gracon Contracting Co., an entity over which Mr. Miller exercises control, 28,000 shares issuable pursuant to presently exercisable options, 100,000 shares issuable pursuant to presently exercisable warrants, and 100,000 units.
- (3) Includes 499,552 shares held by Adel A. Mikhail and Narguis Mikhail, Mr. Mikhail's spouse, as joint tenants and 240,000 shares issuable pursuant to presently exercisable warrants.
- (4) Includes 126,000 shares held by Graphite Enterprise Trust Limited Partnership, an entity over which Foreign & Colonial Enterprise Trust PLC exercises control.
- (5) Includes 16,212 shares owned by Mercé V. Electromedicina, S.L., which Mr. Mercé Vives founded.
- (6) Includes 35,500 shares issuable pursuant to presently exercisable options.
- (7) Includes 300,000 shares issuable pursuant to presently exercisable options.
- (8) Includes 28,000 shares issuable pursuant to presently exercisable options. Mr. Mercé Cervelló is the son of Mr. Mercé Vives and is the Managing and General Director of Mercé V. Electromedicina, S.L.
- (9) Includes 40,000 shares issuable pursuant to presently exercisable options.
- (10) Includes 28,000 shares issuable pursuant to presently exercisable options.
- (11) Represents shares issuable pursuant to presently exercisable options.
- (12) Includes 483,500 shares issuable pursuant to presently exercisable options and 340,000 shares issuable pursuant to presently exercisable warrants.

Certain shares, options and warrants beneficially owned by our officers, directors, significant shareholders and employees are subject to an escrow agreement with the Commissioner of Commerce for the State of Minnesota. The depositors, who placed an aggregate of 1,664,845 shares into escrow, entered into this escrow agreement as a condition of the registration of the units sold in our initial public offering. The term of escrow runs through November 20, 2004.

## Equity Compensation Plan Information

The following table provides information as of the end of the most recently completed fiscal year with respect to compensation plans under which our equity securities are authorized for issuance.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
<b>Equity compensation plans approved by security holders.....</b>	1,039,890	\$ 3.58	655,534(1)
<b>Equity compensation plans not approved by security holders.....</b>	510,000(2)	\$ 3.57	0
<b>Total</b>	<b>1,549,890</b>	<b>\$ 3.58</b>	<b>655,534</b>

(1) Represents 77,000 shares remaining available for future issuance under our 1993 Director Stock Option Plan and 578,534 shares remaining available for future issuance under our 2001 Equity Incentive Plan.

(2) Represents (a) 240,000 shares of common stock underlying a five-year warrant exercisable at \$2.125 per share issued to Adel A. Mikhail, Ph.D., a director and our former chief executive officer, on February 2, 2001, pursuant to a severance and consulting agreement dated November 1, 2000; (b) an aggregate of 100,000 shares of common stock underlying warrants exercisable at \$2.00 per share issued to Paul K. Miller, a director, on November 22, 1999 and December 6, 2000, in connection with Mr. Miller's guarantee of a bank loan, both of which warrants expire on November 19, 2004; (c) 20,000 shares of common stock underlying warrants exercisable at \$5.00 per share issued to Dominick & Dominick in 1997, in consideration for investment banking services, which warrant expired on June 1, 2002; and (d) 150,000 units underlying a warrant exercisable at \$6.75 per unit issued to Equity Securities Investments, Inc. on November 20, 2001, in connection with its services as underwriter of our initial public offering.

## ITEM 12 CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

We entered into a separation agreement and release effective as of November 1, 2000 with Adel A. Mikhail, Ph.D. Dr. Mikhail was our founder and served as our President and Chief Executive Officer from March 1992 until June 15, 2001, at which time he retired. Under the terms of the separation agreement, Dr. Mikhail's employment under his employment agreement dated January 1, 1995 terminated, and we agreed to pay him severance compensation in cash totaling \$144,000. We agreed to pay Dr. Mikhail his salary and benefits until a new chief executive officer was hired and to continue his chairmanship of our board. At the time of entering into the separation agreement, Dr. Mikhail had vested stock options to purchase an aggregate of 420,000 shares of our common stock at an exercise price of \$1.375 per share, expiring on February 2, 2001. Under the separation agreement, Dr. Mikhail agreed to exercise the option to the extent of 30,000 shares for \$41,250 in cash and to surrender 240,000 shares which he otherwise would have been entitled to purchase under the option. We agreed to allow Dr. Mikhail to exercise his option for the remaining 150,000 shares on a cashless basis. In connection with such cashless conversion, we issued 67,500 shares to Dr. Mikhail and Dr. Mikhail surrendered 82,500 shares which he otherwise would have been entitled to purchase under the option. On February 1, 2001, we also issued a five-year warrant to Dr. Mikhail for the purchase of 240,000 shares of common stock exercisable at \$2.125 per share.

The separation agreement further provided that following the termination of his employment as President and Chief Executive Officer, we would retain Dr. Mikhail as an independent consultant for a period of two years to provide advice and technical expertise with respect to our operations. Dr. Mikhail has agreed to provide up to 40 hours of consulting services per month, for a retainer of \$6,000 per month. If additional service is provided beyond 40 hours per month, we will pay Dr. Mikhail at the rate of \$125 per hour, up to a maximum of \$1,000 per day. Dr. Mikhail began providing consulting services to us under this agreement beginning June 15, 2001.

In August 1999, we obtained a bank line of credit from Riverside Bank, which was subsequently acquired by Associated Bank Minnesota. The loan was extended to us on the condition that it be personally guaranteed by Paul K. Miller, one of our directors and our largest individual shareholder. Under an agreement we entered into on August 31, 1999, Mr. Miller personally guaranteed such indebtedness. To induce Mr. Miller to guarantee such indebtedness, we paid Mr. Miller a one-time guarantee fee in the amount of \$75,000 and issued to him, on November 22, 1999 and December 6, 2000, warrants to purchase an aggregate of 100,000 shares exercisable at \$2.00 per share. These warrants expire on November 19, 2004.

We sell heart valves through a distribution network of approximately 35 exclusive distributors, including Mercé V. Electromedicina, S.L., Pro-Medica and formerly N.G.C. Medical S.p.A. The following information relates to sales to such parties over our last two fiscal years. We anticipate that we will continue to do business with Mercé V. Electromedicina and Pro-Medica in future periods.

- Salvador Mercé Vives owns more than 5 percent of our outstanding common stock and is one of our former board members. He founded Mercé V. Electromedicina. Salvador Mercé Cervelló, one of our current directors and the son of Salvador Mercé Vives, serves as Managing and General Director of Mercé V. Electromedicina. During our fiscal year ended April 30, 2002, Mercé V. Electromedicina purchased \$1,421,960 of product from our company, representing 47.5 percent of our net sales. During our fiscal year ended April 30, 2001, Mercé V. Electromedicina purchased \$1,170,700 of product from our company, representing 40.9 percent of our net sales.
- Hilmar Siebecker owns more than 5 percent of our outstanding common stock and is the President of Pro-Medica. During our fiscal year ended April 30, 2002, Pro-Medica purchased \$13,300 of product from our company, representing 0.4 percent of our net sales. During our fiscal year ended April 30, 2001, Pro-Medica did not purchase product from our company.
- Eugenio Cremascoli, one of our former directors, is President and Chief Executive Officer of N.G.C. Medical, a former distributor which owns more than 5 percent of our outstanding common stock. During our fiscal year ended April 30, 2002, N.G.C. Medical purchased \$15,300 of product from our company, representing 0.5 percent of our net sales. During our fiscal year ended April 30, 2001, N.G.C. Medical purchased \$130,980 of product from our company, representing 4.6 percent of our net sales.

On June 1, 2000, we granted Ronald M. Bosrock, one of our directors, an option to purchase 10,000 shares of our common stock at \$2.50 per share under our 1997 Stock Option Plan. This option is exercisable for four years and vested at the time of grant. We granted this option in consideration of Mr. Bosrock's efforts to complete the spin-off of UROPACE. Under the terms of the Agreement and Plan of Reorganization and Corporate Separation between our company and UROPACE, dated November 1, 2000, UROPACE assumed consulting fees of \$5,000 per month payable to Mr. Bosrock and granted him an option to purchase 40,000 shares of its common stock at \$0.01 per share. This option is exercisable for four years and vested at the time of grant. Following completion of the spin-off, Mr. Bosrock became the acting Chief Executive Officer of UROPACE.

Certain individuals have employment agreements with us. You should review Management — Employment Agreements for more information about such agreements.

The transactions set forth herein were approved by a majority of our independent, disinterested directors who had access, at our expense, to our legal counsel or independent legal counsel. We believe that all such transactions were made on terms no less favorable to us than we could have obtained from unaffiliated third parties. In the future, all material affiliated transactions and loans, and any forgiveness of loans, will be approved by a majority of our independent, disinterested directors who will have access, at our expense, to our legal counsel or independent legal counsel and will be on terms no less favorable to us than we could obtain from unaffiliated third parties.

We have no current plans to issue preferred stock. However, should we determine to issue preferred stock, we will offer such stock to persons who are considered promoters of our company only if the preferred stock is offered on the same terms to all other existing shareholders or to new shareholders, or the issuance of preferred stock is approved by a majority of our independent, disinterested directors who have access, at our expense, to our legal counsel or independent legal counsel.

**ITEM 13      EXHIBITS, LIST AND REPORTS ON FORM 8-K**

(a)      Exhibits

See "Index to Exhibits."

(b)      Reports on Form 8-K

We filed no Current Reports on Form 8-K during the quarter ended April 30, 2002.

## SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Inver Grove Heights, State of Minnesota, on July 29, 2002.

MedicalCV, Inc.

By /s/ Blair P. Mowery

Blair P. Mowery

President, Chief Executive Officer and Director  
(Principal Executive Officer)

## POWER OF ATTORNEY

KNOW ALL BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Blair P. Mowery and Jules L. Fisher as his or her true and lawful attorney-in-fact and agent, with full powers of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any or all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant, and in the capacities and on the date indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Blair P. Mowery</u> Blair P. Mowery	President, Chief Executive Officer and Director (Principal Executive Officer)	July 29, 2002
<u>/s/ Jules L. Fisher</u> Jules L. Fisher	Chief Financial Officer (Principal Accounting Officer and Principal Financial Officer)	July 29, 2002
<u>/s/ Adel A. Mikhail, Ph.D.</u> Adel A. Mikhail, Ph.D.	Chairman of the Board	July 29, 2002
<u>/s/ Ronald M. Bosrock</u> Ronald M. Bosrock	Director	July 29, 2002
<u>/s/ Salvador Mercé Cervelló</u> Salvador Mercé Cervelló	Director	July 29, 2002
<u>/s/ Norman Dann</u> Norman Dann	Director	July 29, 2002
<u>/s/ Richard A. DeWall, M.D.</u> Richard A. DeWall, M.D.	Director	July 29, 2002
<u>/s/ Paul K. Miller</u> Paul K. Miller	Director	July 29, 2002

## INDEX TO EXHIBITS

Exhibit Number	Description
3.1	Restated Articles of Incorporation of the Registrant (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
3.2	Bylaws of the Registrant (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen common stock certificate (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
4.3	Form of Warrant Agreement (including specimen Class A Warrant certificate) (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
4.4	Specimen unit certificate (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.1	Separation Agreement and Release by and between the Registrant and Adel A. Mikhail, effective November 1, 2000 (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.2	1992 Stock Option Plan (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.3	1993 Director Stock Option Plan (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.4	1997 Stock Option Plan (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.5	2001 Equity Incentive Plan (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.6	Warrant Agreement by and between the Registrant and Paul K. Miller, dated November 22, 1999 (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.7	Warrant Agreement by and between the Registrant and Adel A. Mikhail, dated February 2, 2001 (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.8	Warrant Agreement by and between the Registrant and Paul K. Miller, dated December 6, 2000 (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.9	Form of Escrow Agreement by and between the Registrant, Paul K. Miller, Adel A. Mikhail, Ph.D., Salvador Mercé Vives, Mercé V. Electromedicina S.L., Richard A. DeWall, M.D., Blair P. Mowery, Salvador Mercé Cervelló, Allan R. Seck, Norman Dann, Ronald M. Bosrock, George M. Wettstaedt, Gene E. Stobbs, Shelley Johnson, Associated Trust Company National Association and the Commissioner of Commerce for the State of Minnesota (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.10	O.E.M. Supply Contract by and between the Registrant and Sulzer Carbomedics, Inc., effective July 24, 1998 (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).*
10.11	First Amendment to Supply Agreement by and between the Registrant and Sulzer Carbomedics, Inc., effective March 6, 2001 (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).*
10.12	Promissory Note in the principal amount of \$2,500,000, issued by the Registrant, maker, to Associated Bank Minnesota, payee, dated November 23, 1999 (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.13	Commitment Letter by and between Associated Bank Minnesota, lender, and the Registrant, borrower, dated August 26, 1999, pertaining to proposed revised line of credit terms (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.14	Working Capital Line of Credit — Change in Terms Agreement by and between Associated Bank Minnesota, lender, and the Registrant, borrower, dated November 23, 2000 (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.15	Correspondence from Associated Bank Minnesota to the Registrant, dated December 11, 2000, extending the line of credit maturity date (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.16	Correspondence to Paul Miller, dated August 31, 1999, regarding the Registrant's compensation to Mr. Miller for his personal guarantee of the Associated Bank Minnesota line of credit (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.17	Amendment to Working Capital Line of Credit by and between Associated Bank Minnesota, lender, and the Registrant, borrower, dated August 24, 2001 (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.18	Employment Agreement by and between the Registrant and Blair P. Mowery, effective June 15, 2001 (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.19	Letter Agreement by and between the Registrant and Allan R. Seck, dated May 5, 1999 (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
10.20	Amendment to Letter Agreement by and between the Registrant and Allan R. Seck, dated August 30, 2001 (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
16	Letter on change in certifying accountant from Bertram Vallez Kaplan & Talbot Ltd. (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
21	Subsidiaries of the Registrant (incorporated by reference to our Registration Statement on Form SB-2, filed on August 31, 2001 (File No. 333-68884)).
23	Consent of PricewaterhouseCoopers LLP.
24	Power of Attorney (included on signature page to Form 10-KSB).

\* Certain portions of this exhibit are subject to an order granting confidential treatment pursuant to Rule 406.



## **OFFICERS**

Blair P. Mowery

*President and Chief Executive Officer*

Jules L. Fisher

*Chief Financial Officer*

Allan R. Seck

*Senior Vice President, Sales and Marketing*

Dennis E. Steger

*Vice President, Regulatory Affairs/Quality Assurance*

Gene Stobbs

*Vice President, Operations*

Thomas J. McEvoy

*Vice President, Engineering*

Shelley Johnson

*Vice President, Medical Affairs*

## **BOARD OF DIRECTORS**

Susan L. Critzer

*President, Pi Medical*

*Chief Operating Officer, Venturi Group, LLC*

Richard A. DeWall, M.D.

*Retired Cardiothoracic Surgeon*

David B. Kaysen

*Former President and Chief Executive Officer,  
Rehabicare Inc.*

Salvador Mercé Cervelló

*Managing and General Director,  
Mercé v. Electromedicina S.L.*

Adel A. Mikhail, Ph.D.

*Chairman of the Board,  
MedicalCV, Inc.*

Paul K. Miller

*President,  
Acton Construction Management Company*

Blair P. Mowery

*President and Chief Executive Officer,  
MedicalCV, Inc.*

## **CORPORATE DATA AND SHAREHOLDER INFORMATION**

### **Corporate Headquarters**

MedicalCV, Inc.

9725 South Robert Trail

Inver Grove Heights, MN 55077

651-452-3000

### **Auditors**

PricewaterhouseCoopers LLP

650 Third Avenue South, Suite 1300

Minneapolis, MN 55402-4333

### **Legal Counsel**

Briggs and Morgan

2400 IDS Center

Minneapolis, MN 55402

### **Securities**

MedicalCV units are traded on The Nasdaq SmallCap Market under the ticker symbol "MDCVU." Each unit consists of one share of common stock and one redeemable Class A Warrant.

### **Transfer Agent and Registrar**

The transfer agent and registrar for MedicalCV is:  
Registrar and Transfer Company

10 Commerce Drive

Carnford, NJ 07016-3572

### **Annual Meeting**

The annual meeting of shareholders will be held at 3:30 pm on October 2, 2002, at the Minneapolis Club, 729 Second Avenue South, Minneapolis, MN 55402.

### **Financial Information**

MedicalCV financial results and news are available online at [www.medcvinc.com](http://www.medcvinc.com). Shareholders may obtain, without charge, a copy of the Annual Report on Form 10-KSB as filed with the Securities and Exchange Commission for the year ended April 30, 2002, by writing:

Jules L. Fisher,

Chief Financial Officer

MedicalCV, Inc.

9725 South Robert Trail

Inver Grove Heights, MN 55077



MedicalCV, Inc.

9725 South Robert Trail

Inver Grove Heights, Minnesota 55077

651-452-3000

800-328-2060

[www.medcvinc.com](http://www.medcvinc.com)